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(54) **TETHER LINE SYSTEMS AND METHODS FOR TONGUE OR OTHER TISSUE SUSPENSION OR COMPRESSION**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **14/020,617**

(22) Filed: **Sep. 6, 2013**

(65) **Prior Publication Data**

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Related U.S. Application Data

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(51) **Int. Cl.**
A61B 17/06 (2006.01)
A61L 17/14 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 17/06166*** (2013.01); ***A61B 17/0401*** (2013.01); ***A61B 17/0482*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 17/06166; A61B 2017/06171; A61B 2017/0618
USPC 606/228–231, 60; 132/321; 264/167; 128/848, 860; 427/2.29, 2.31
See application file for complete search history.

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Primary Examiner — Todd E Manahan
Assistant Examiner — Charles Wei
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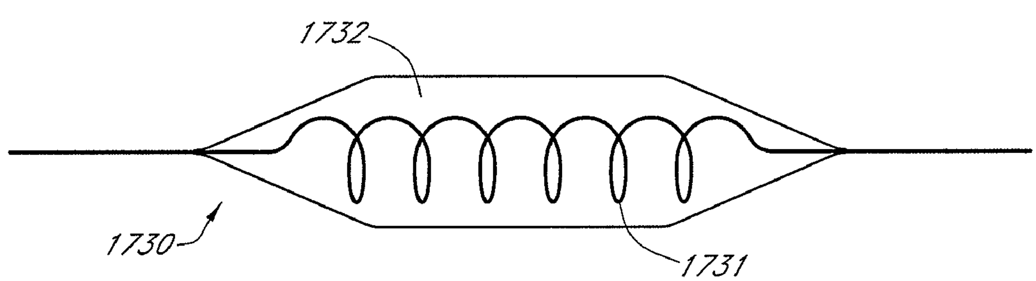
(57) **ABSTRACT**

Systems and methods of placing one or more suture loops into tissue, such as the base of the tongue, are described. A system can include a variable-thickness suspension line for suspending tissue, including a suture having a first thickness dimension; an elastomer surrounding a portion of the suture and defining a central segment of the suspension line having a second thickness dimension greater than the first thickness dimension, and at least one transition zone extending from the central segment of the suspension line to a lateral end of the suspension line, the transition zones having a thickness dimension that tapers from the second thickness dimension to the first thickness dimension.

14 Claims, 35 Drawing Sheets



(51) **Int. Cl.**
A61B 17/04 (2006.01)
A61B 17/12 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B17/0483*** (2013.01); ***A61B 17/0487*** (2013.01); ***A61L 17/145*** (2013.01); *A61B 17/0485* (2013.01); *A61B 17/12013* (2013.01); *A61B 2017/044* (2013.01); *A61B 2017/0414* (2013.01); *A61B 2017/0451* (2013.01); *A61B 2017/0472* (2013.01); *A61B 2017/0618* (2013.01); *A61B 2017/06052* (2013.01); *A61B 2090/3966* (2016.02)

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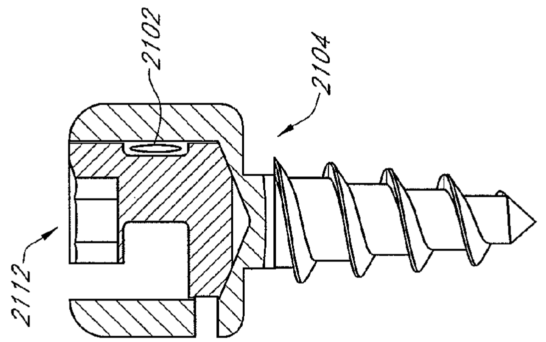


FIG. 1B

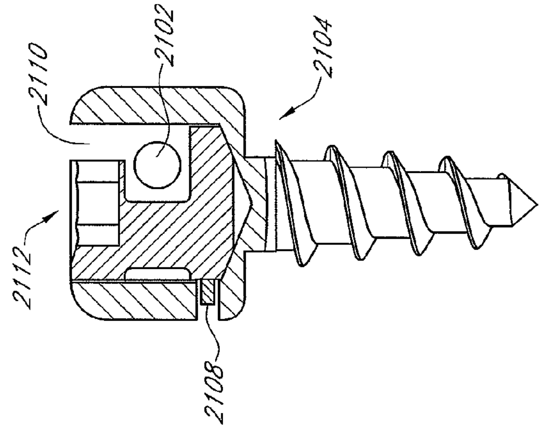
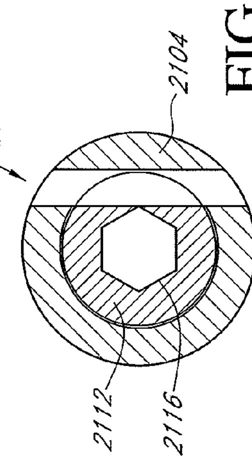


FIG. 1A



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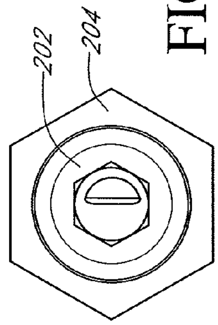
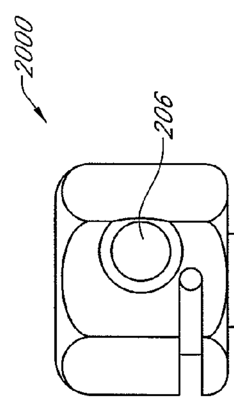


FIG. 2A



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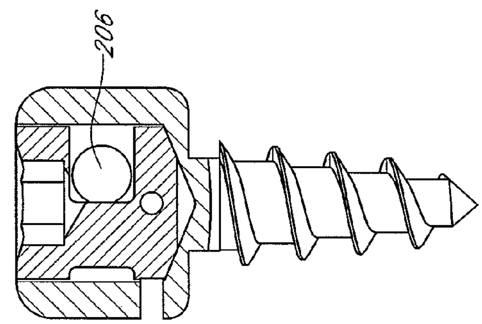

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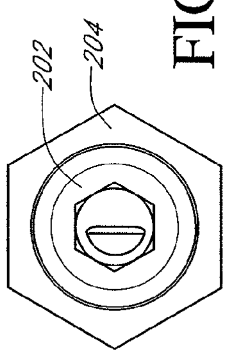

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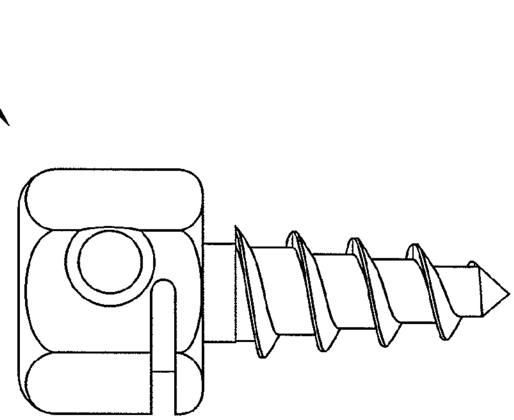

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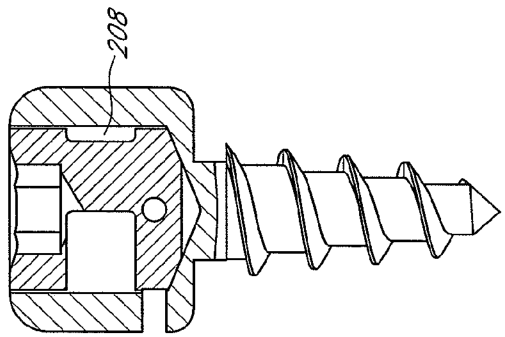

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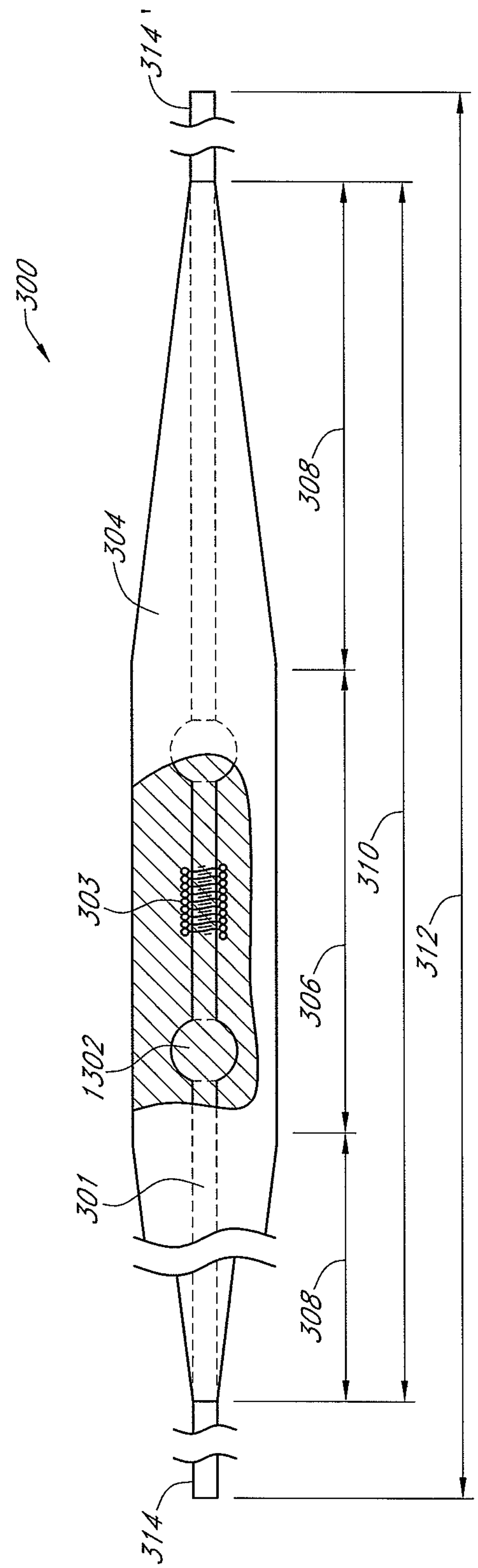
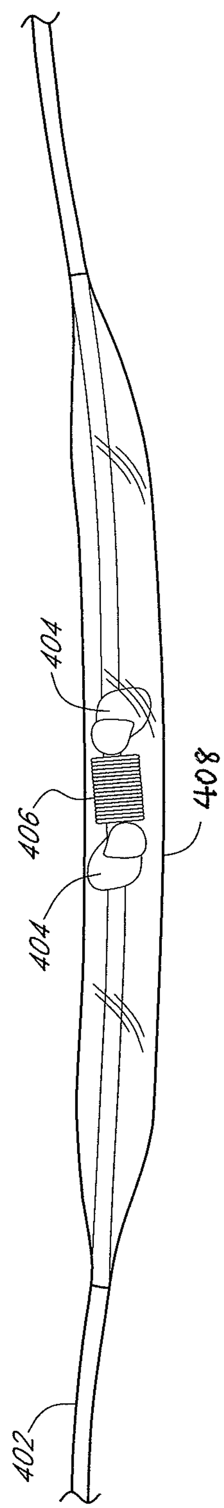


FIG. 3



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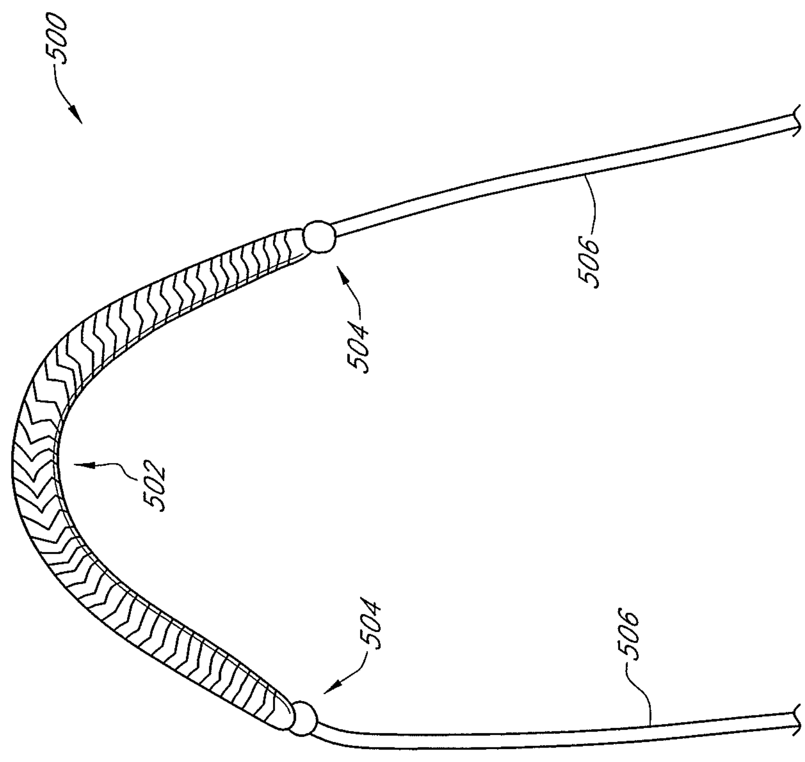

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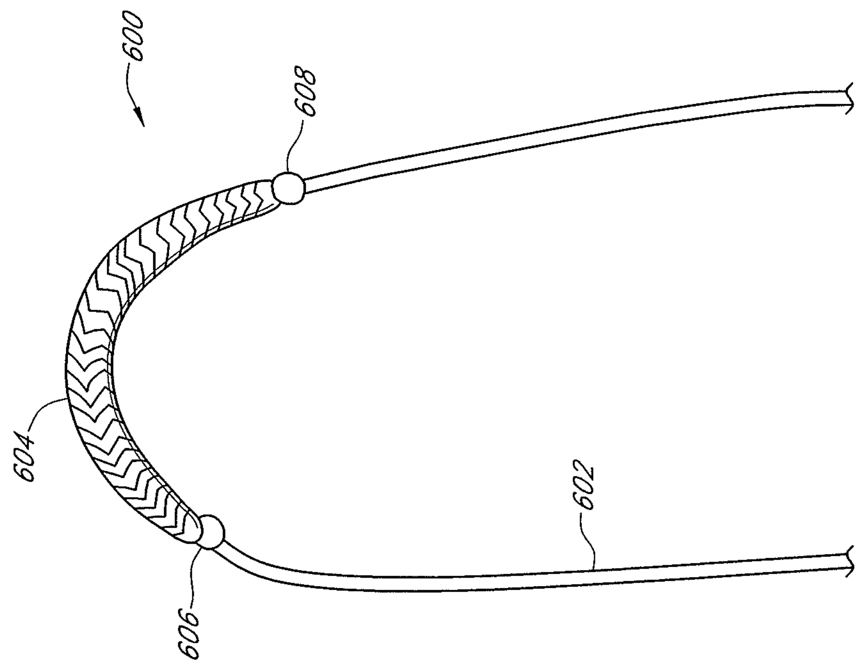

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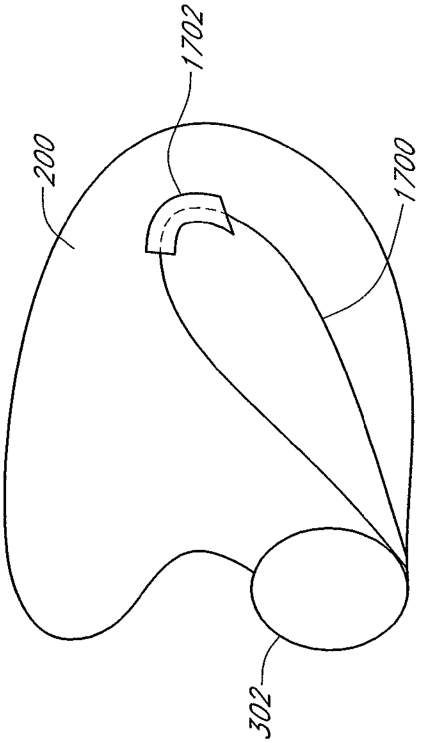
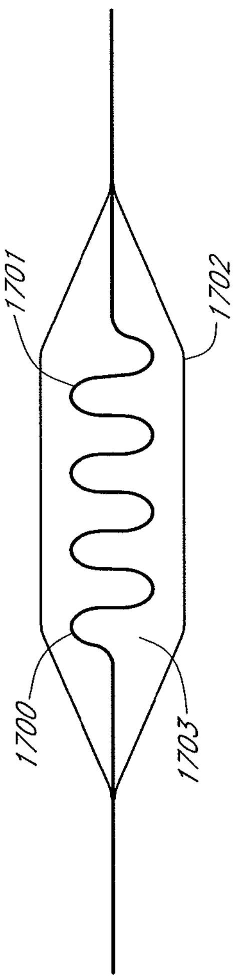


FIG. 7A



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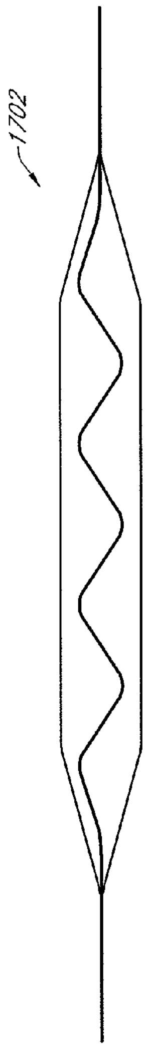

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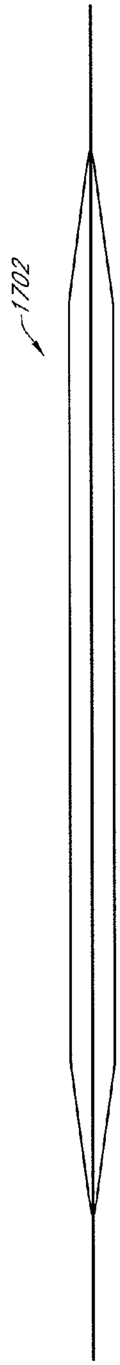


FIG. 7D

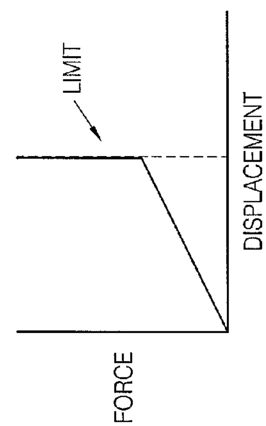
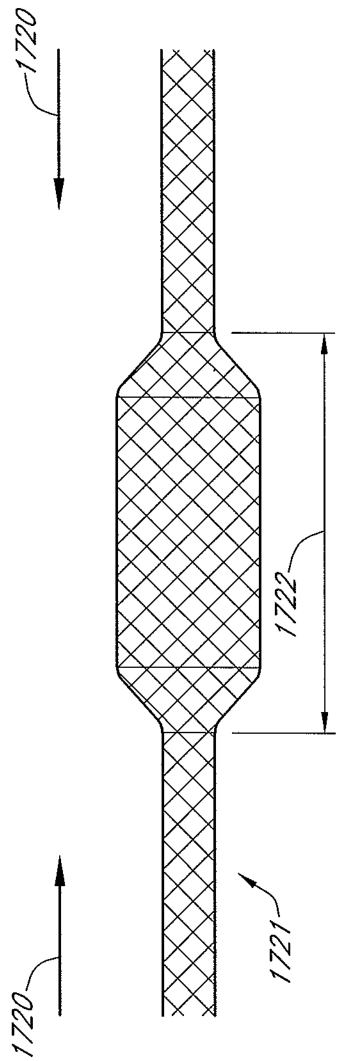


FIG. 7E



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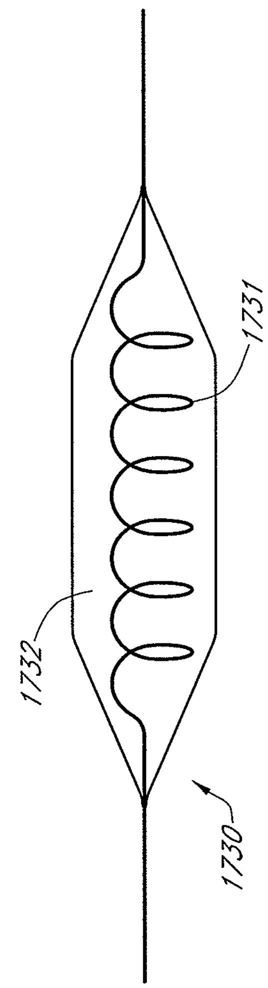

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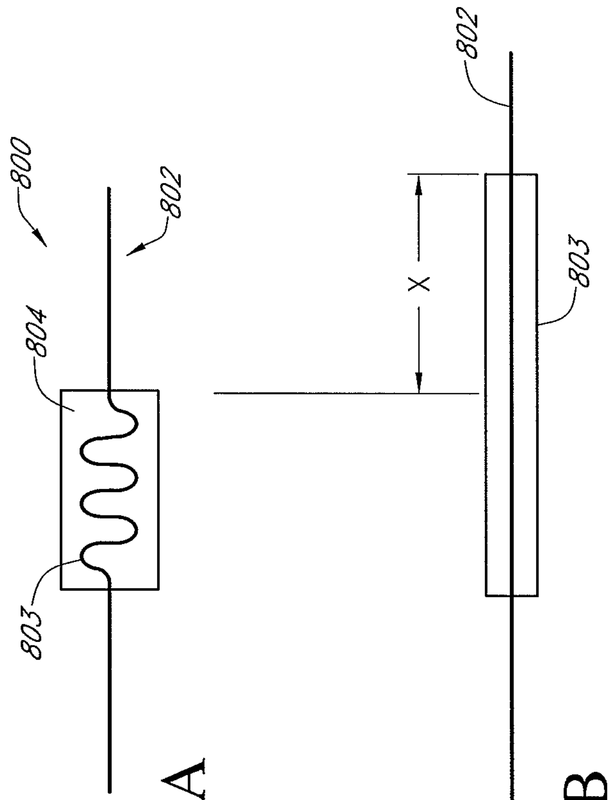

FIG. 8A

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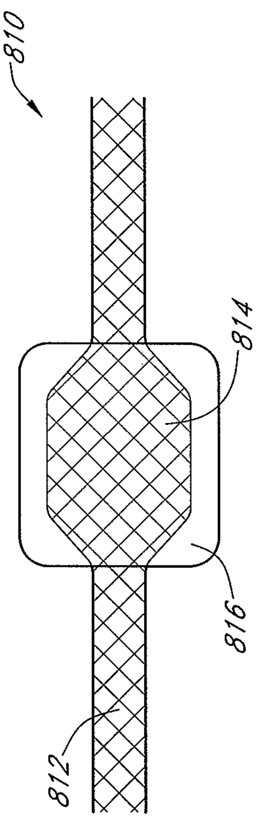

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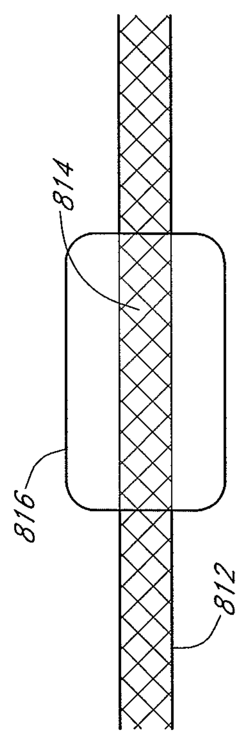

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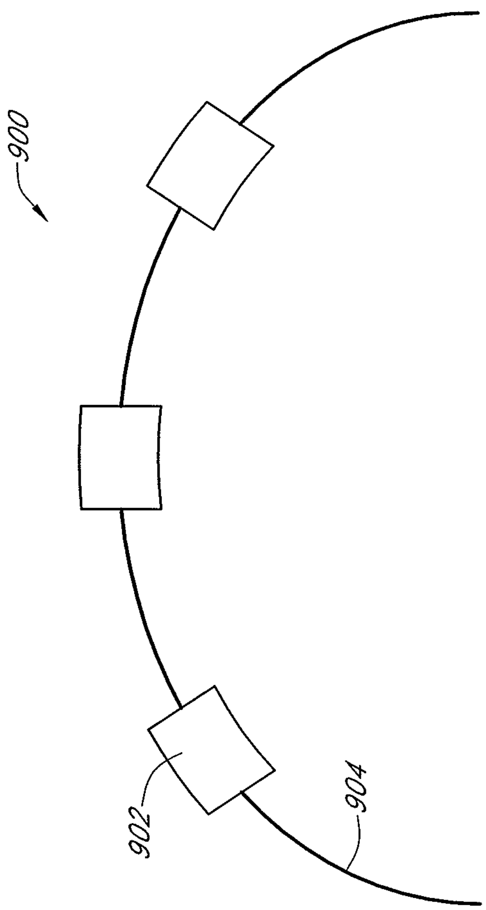
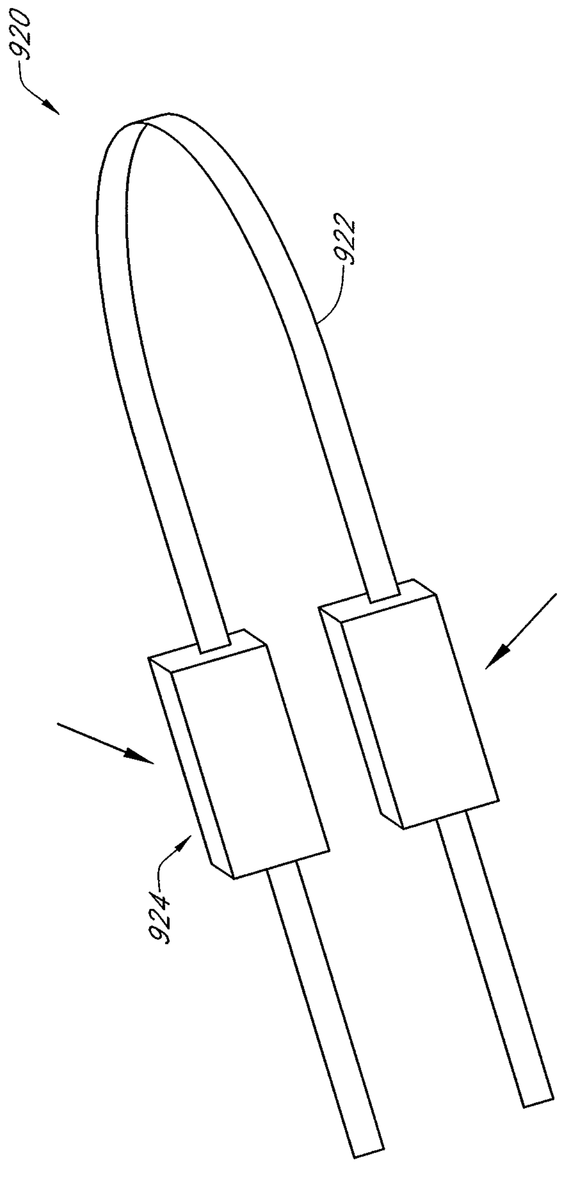


FIG. 9A



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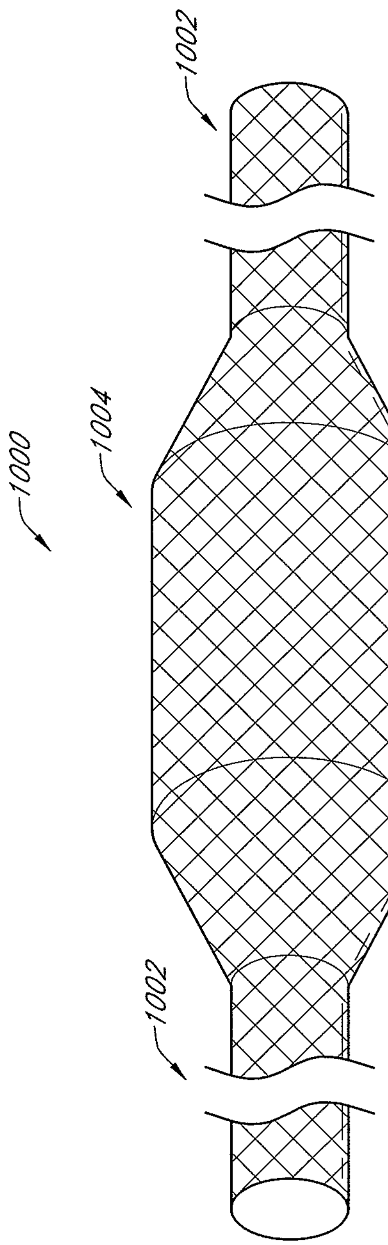

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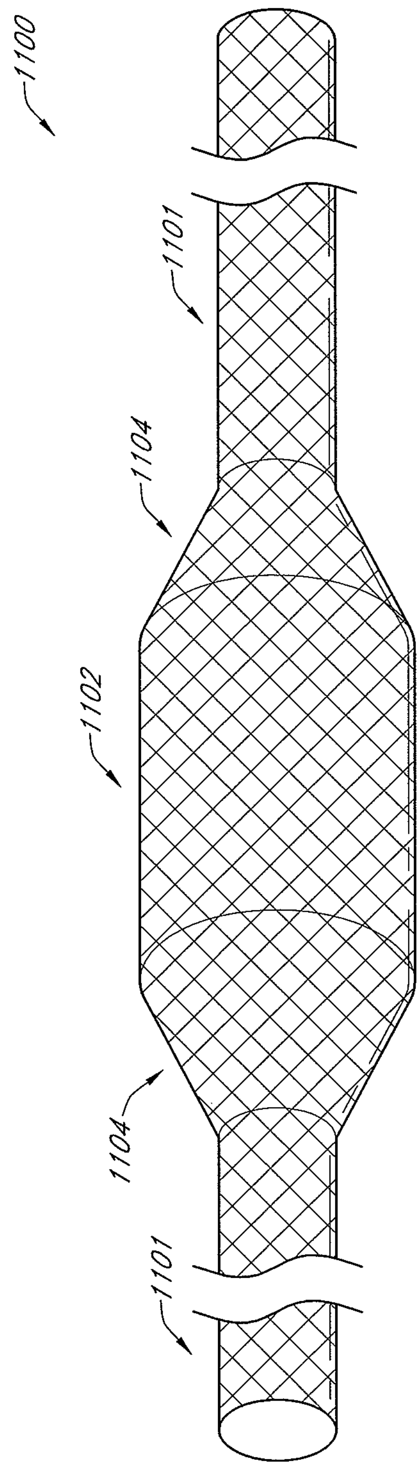

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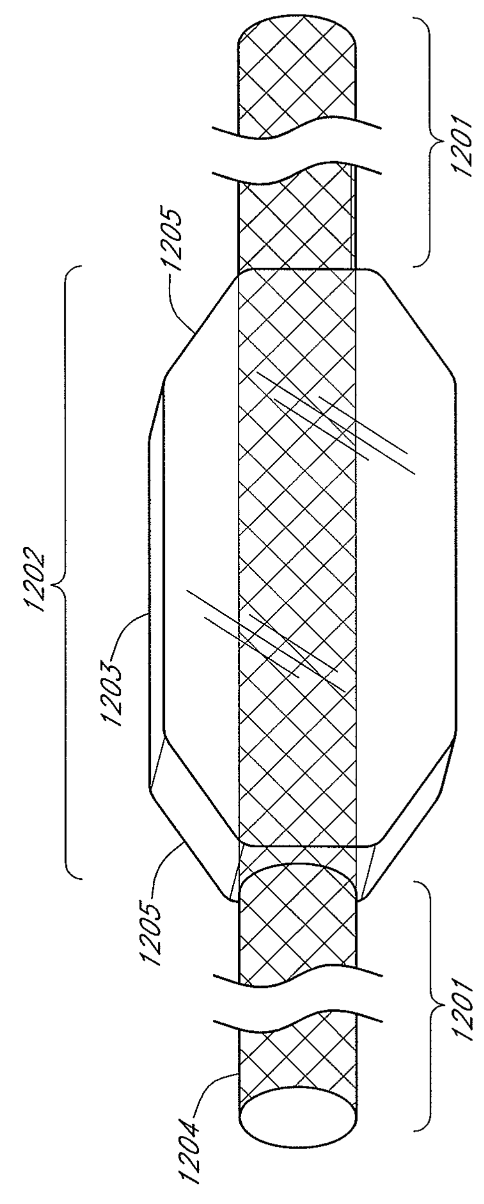

FIG. 12

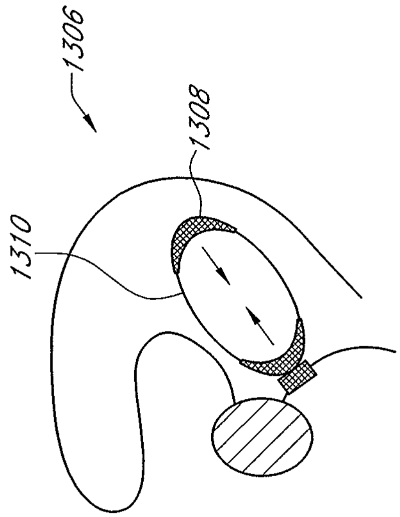

FIG. 13B

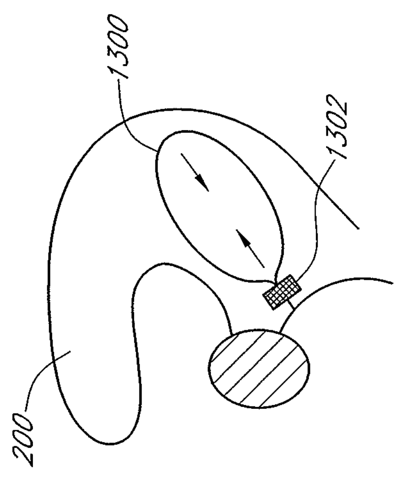

FIG. 13A

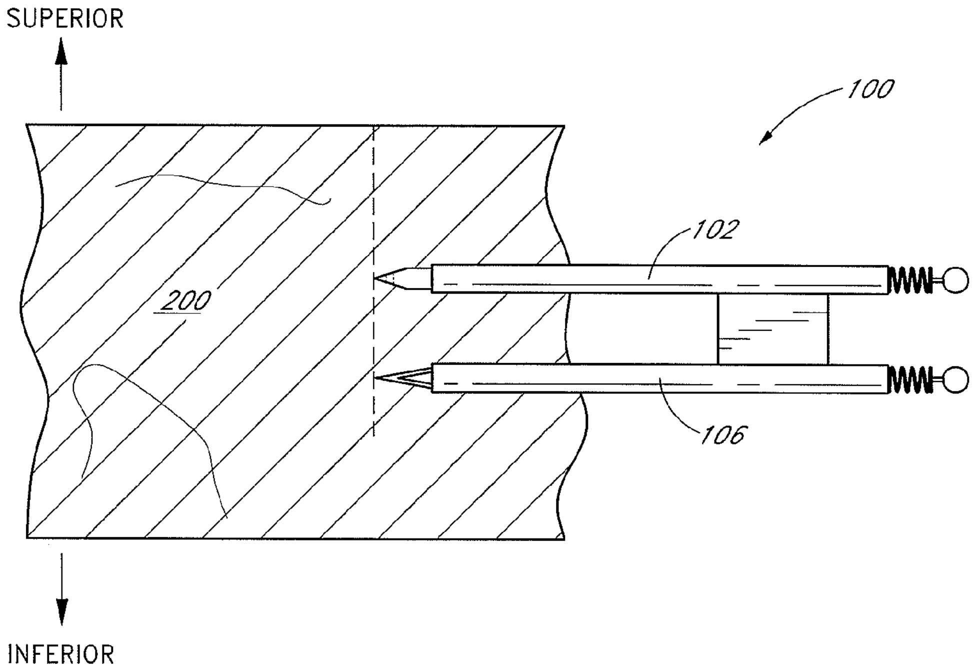
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FIG. 14

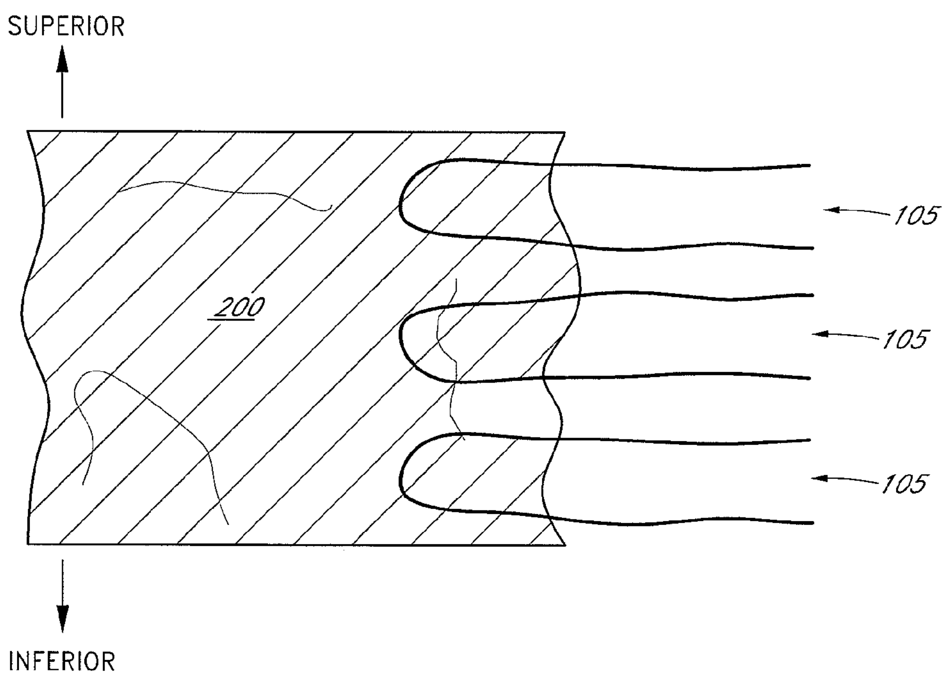
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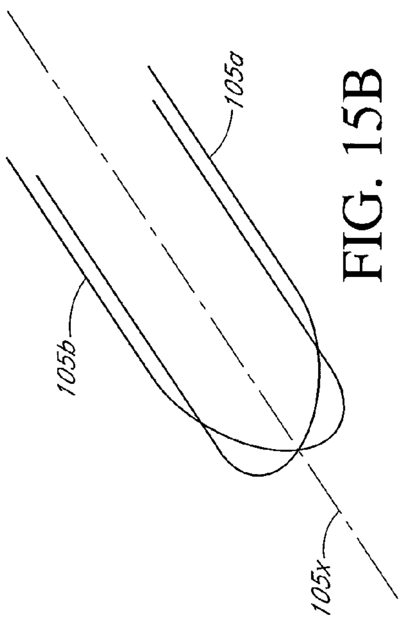
FIG. 15



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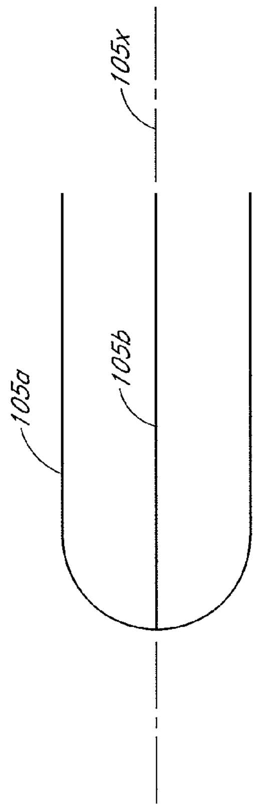

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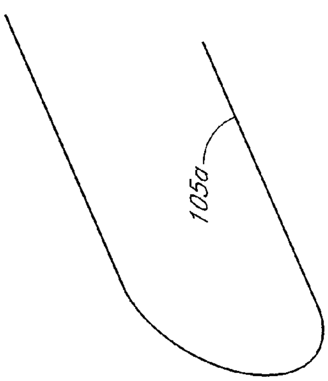

FIG. 15A

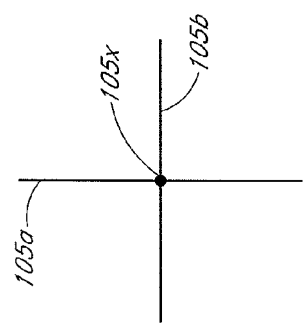

FIG. 15C

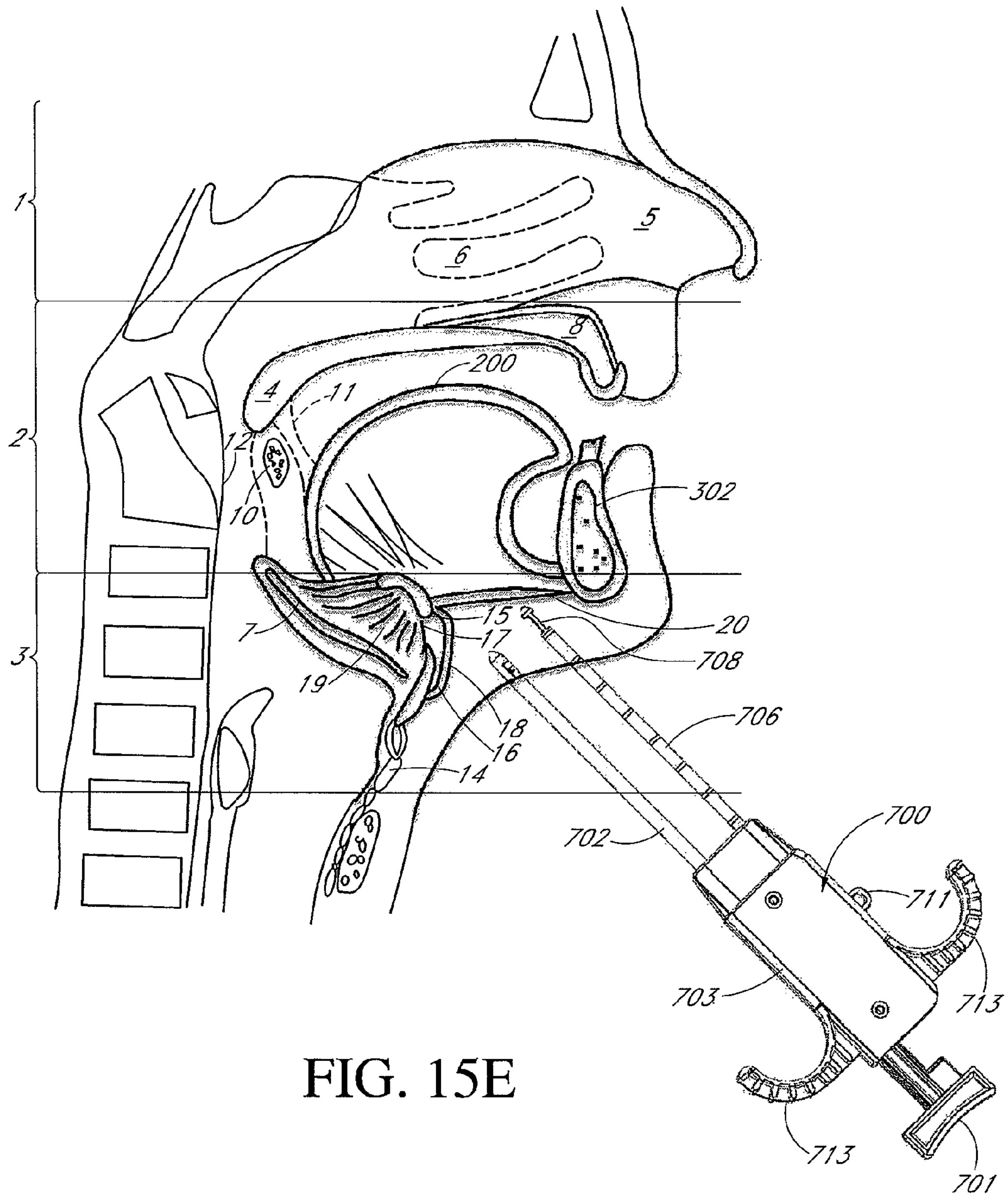
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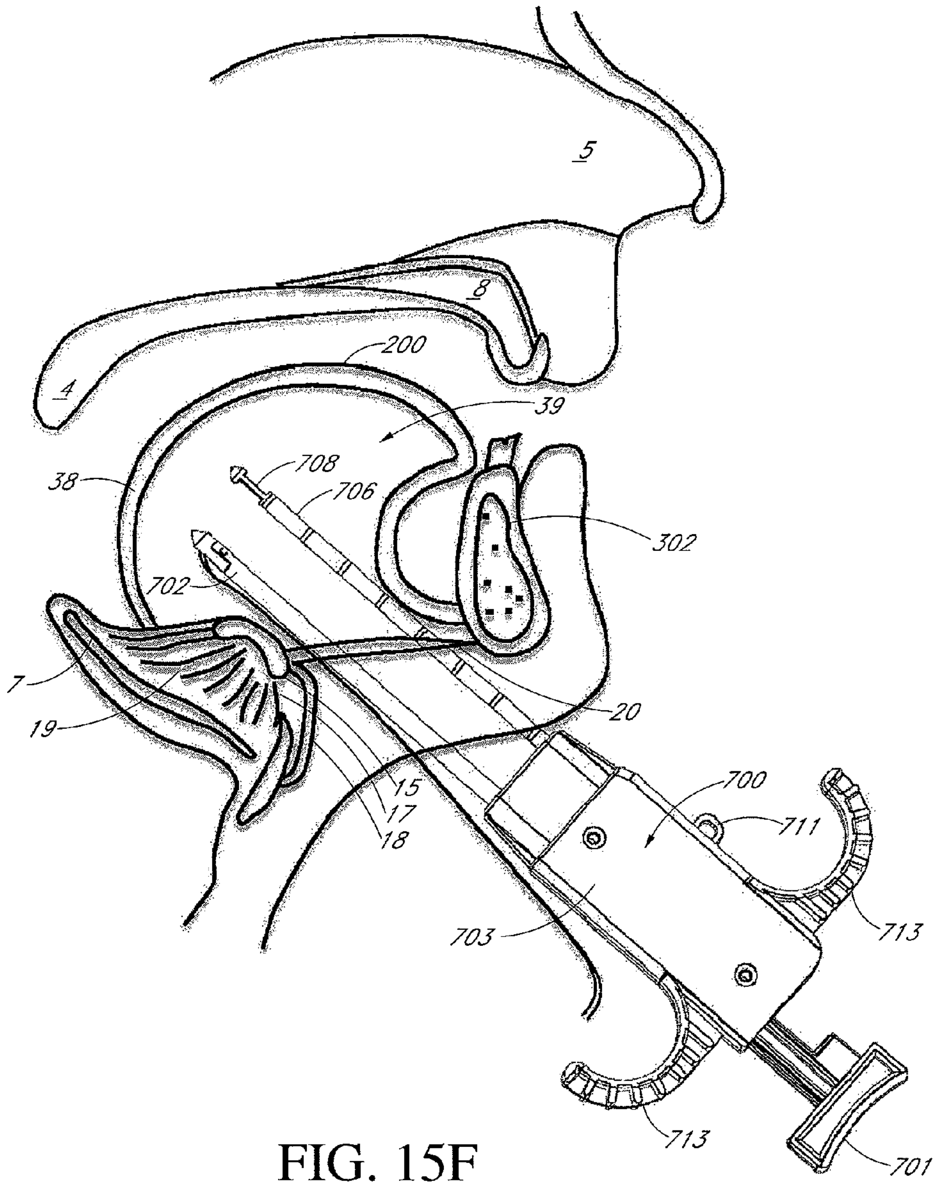
FIG. 15E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18
700
711
713
703
713
701

FIG. 15F

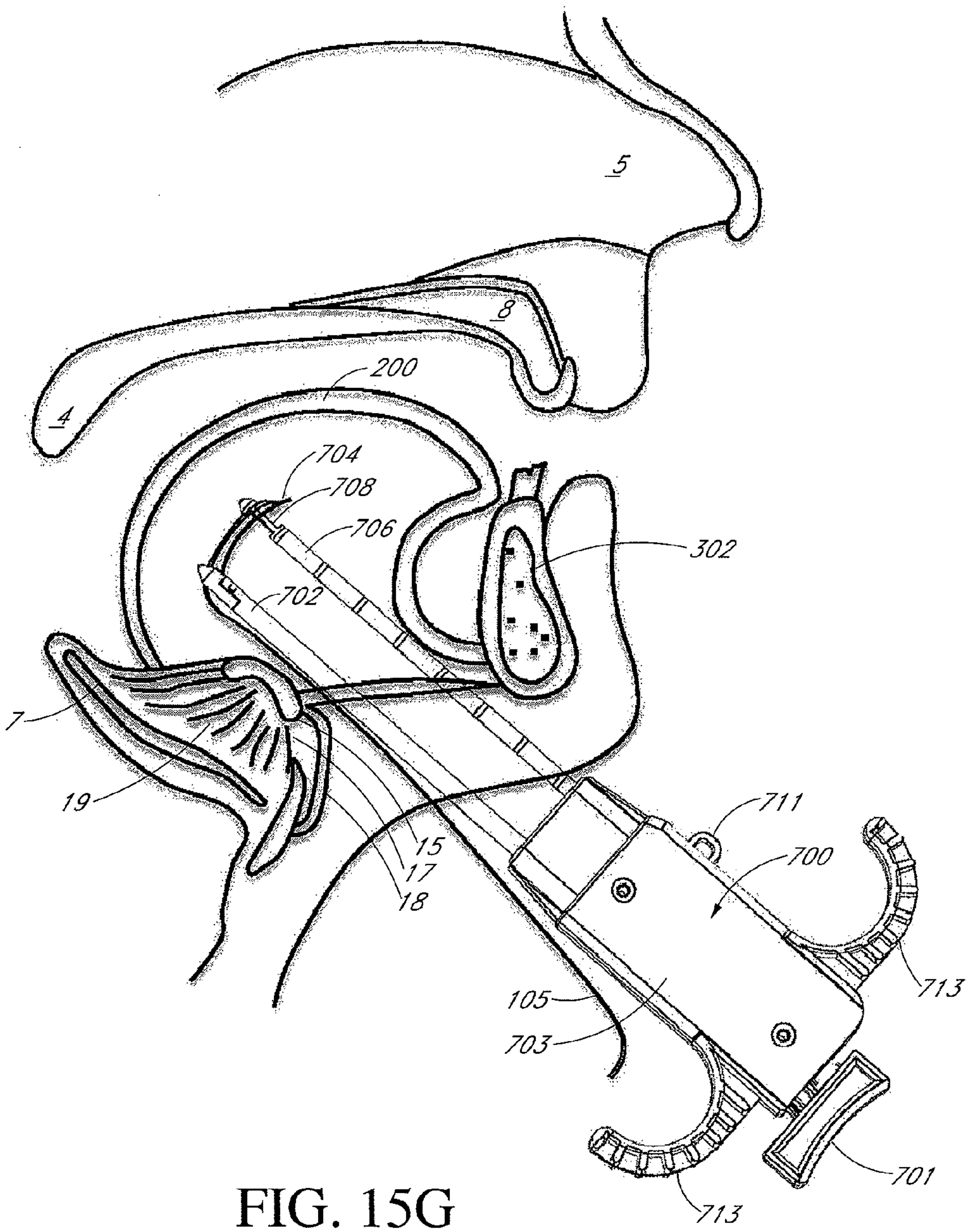

5
8
4
200
704
708
706
702
302
7
19
15
17
18
711
700
713
105
703
713
701

FIG. 15G

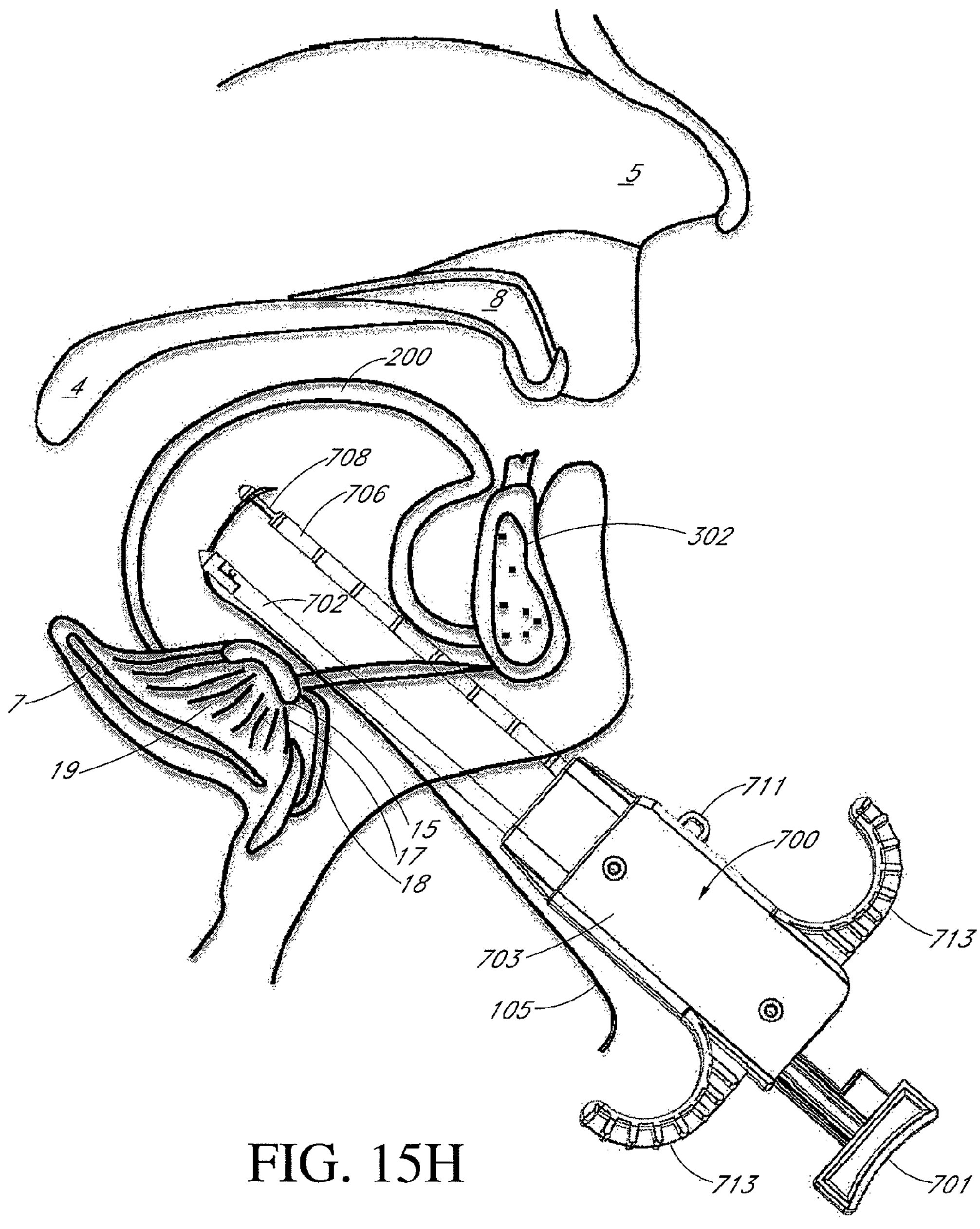
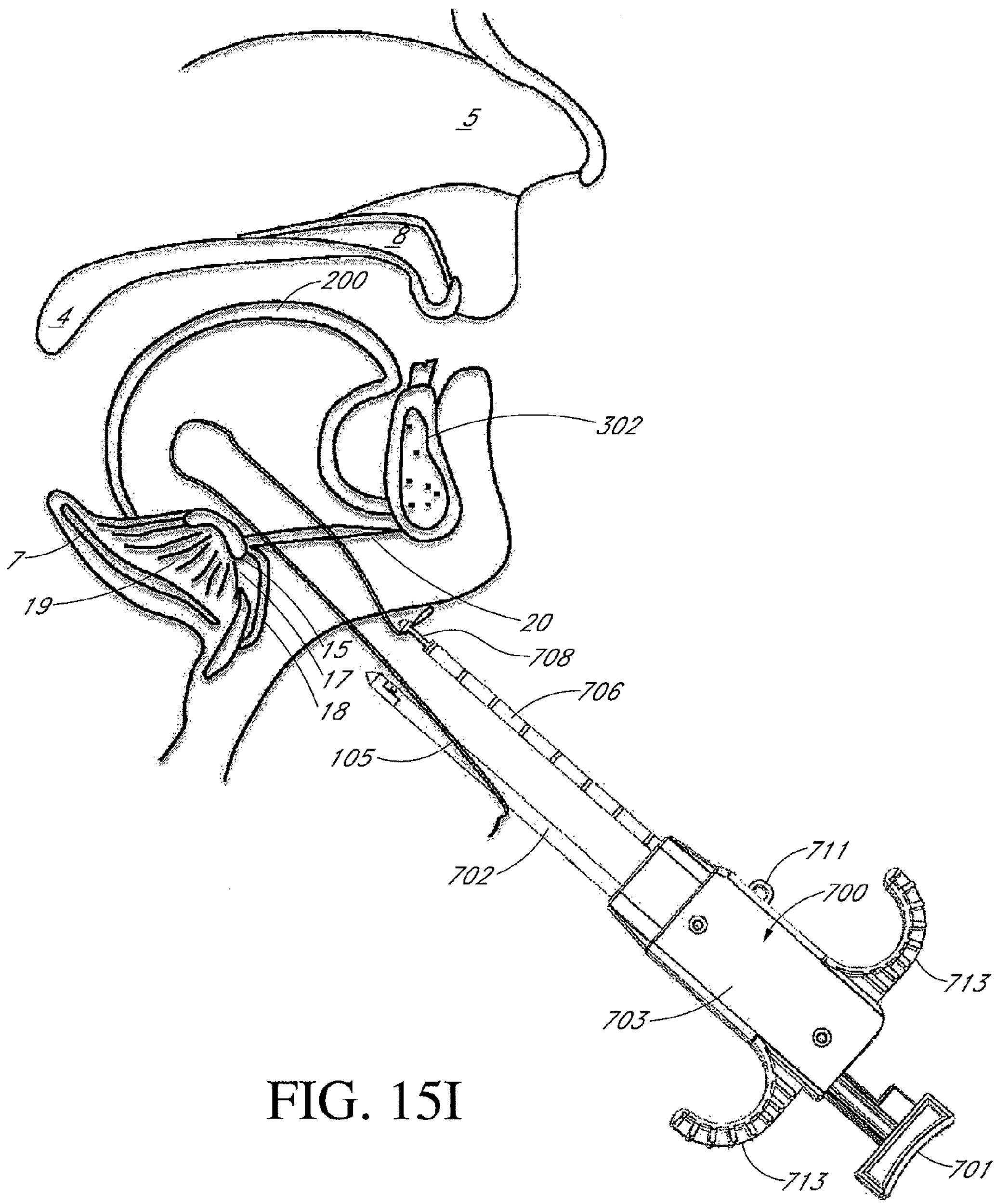


FIG. 15H


5
8
4
200
302
7
19
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708
17
18
706
105
711
702
700
713
703
713
701

FIG. 15I

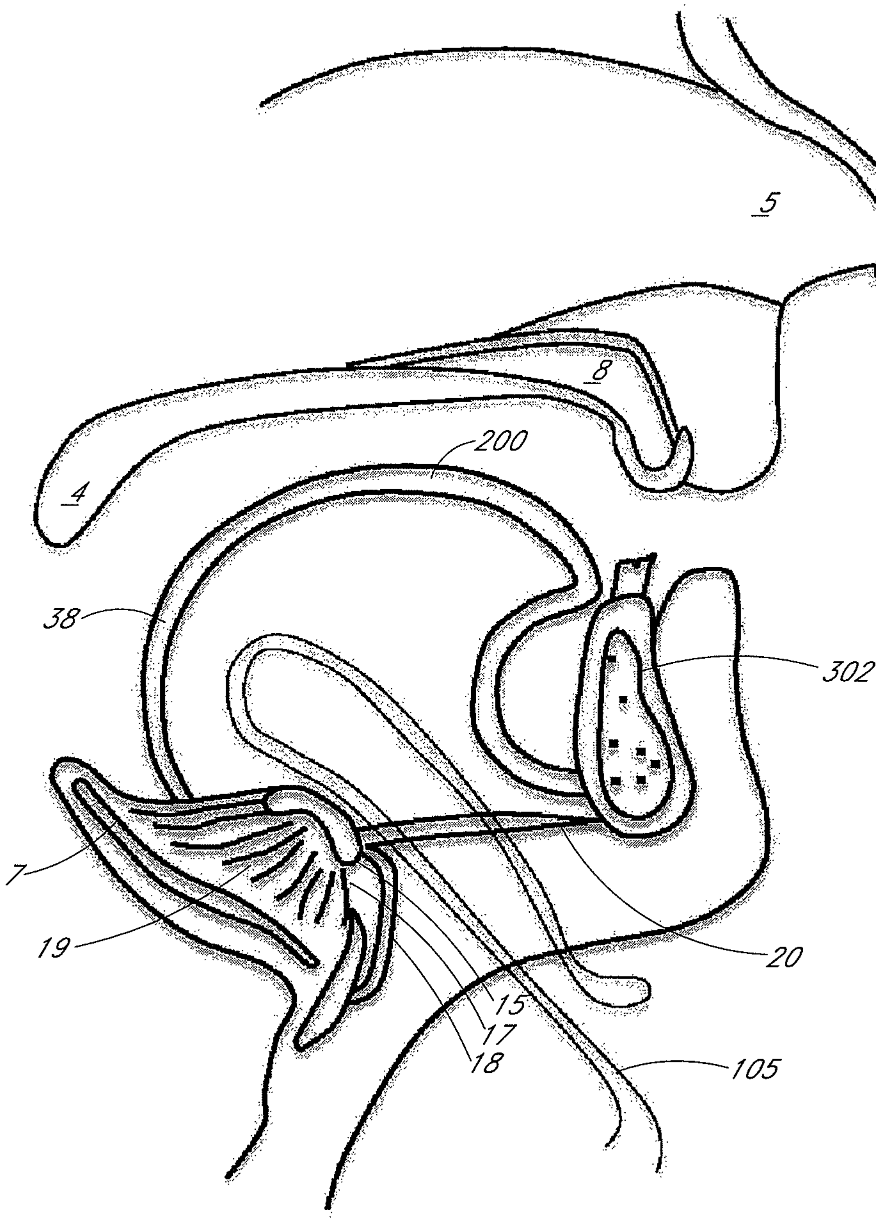

FIG. 15J

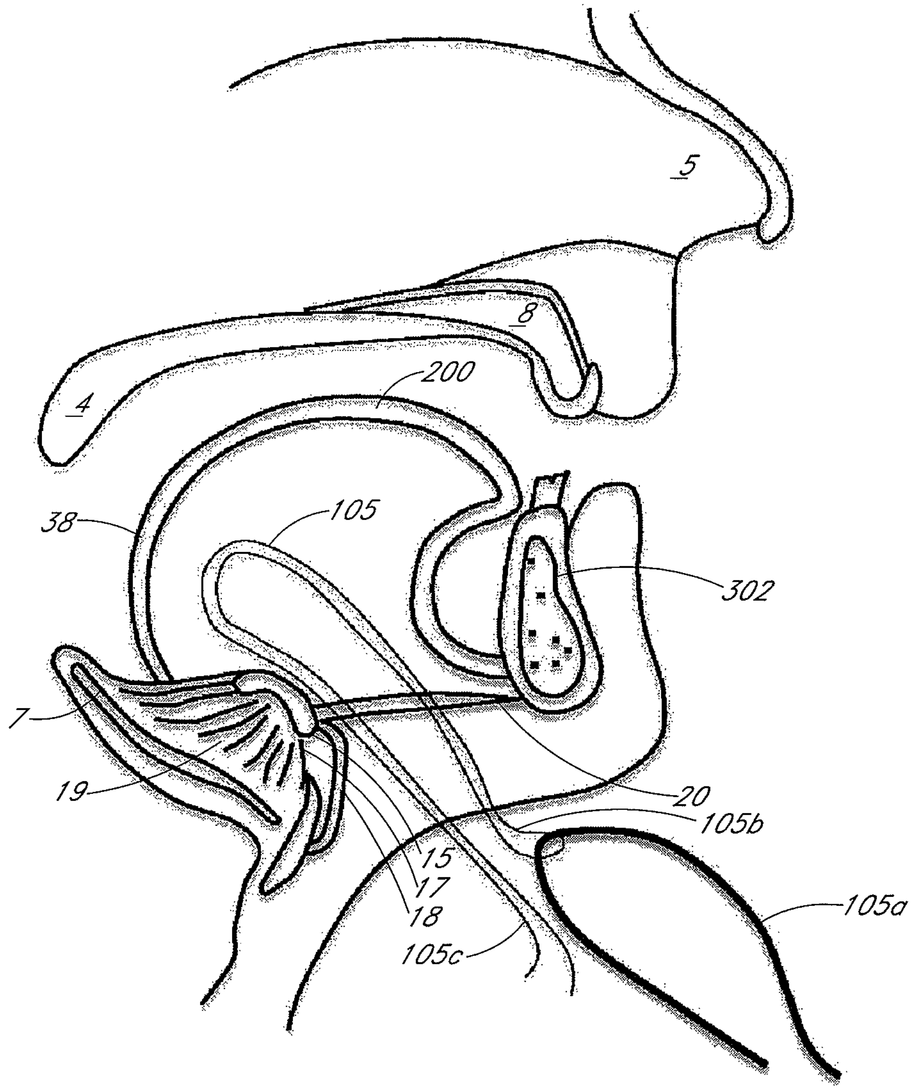

FIG. 15K

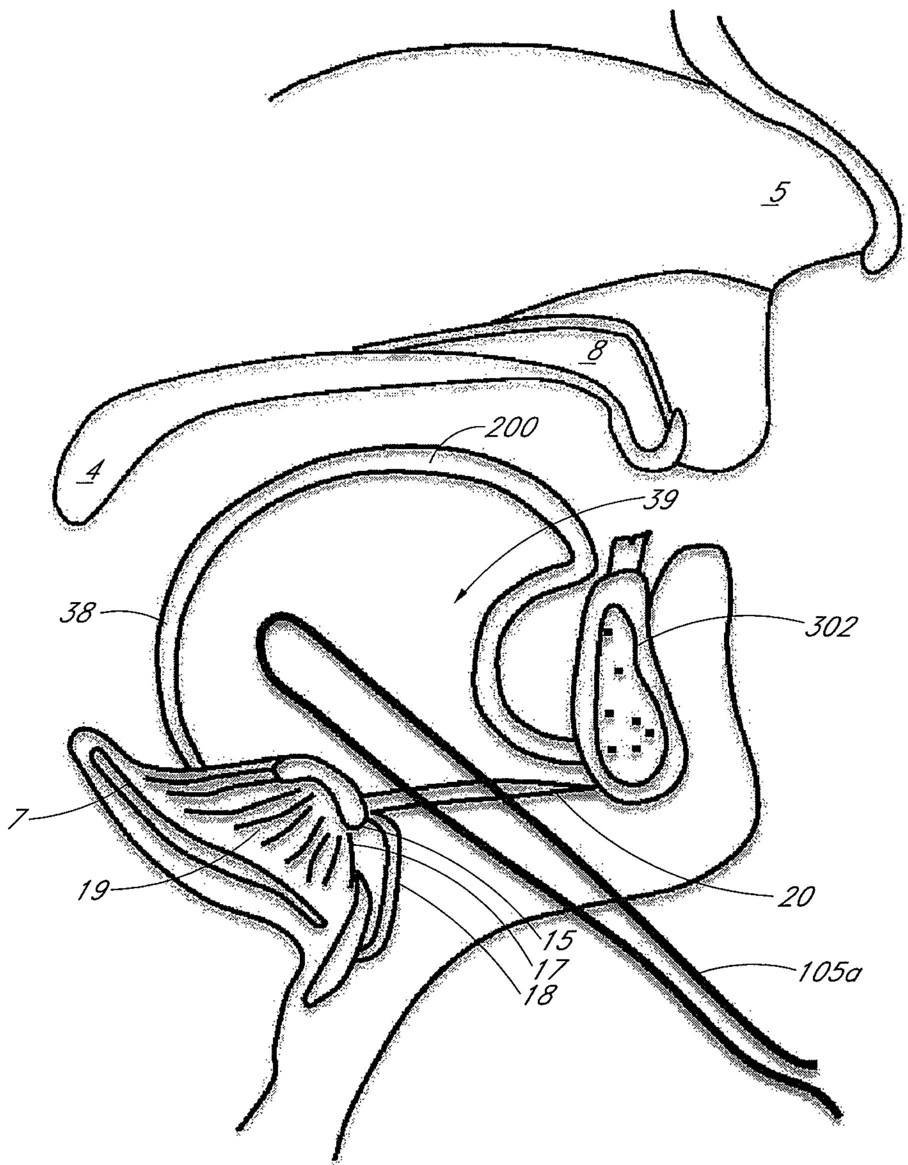

FIG. 15L

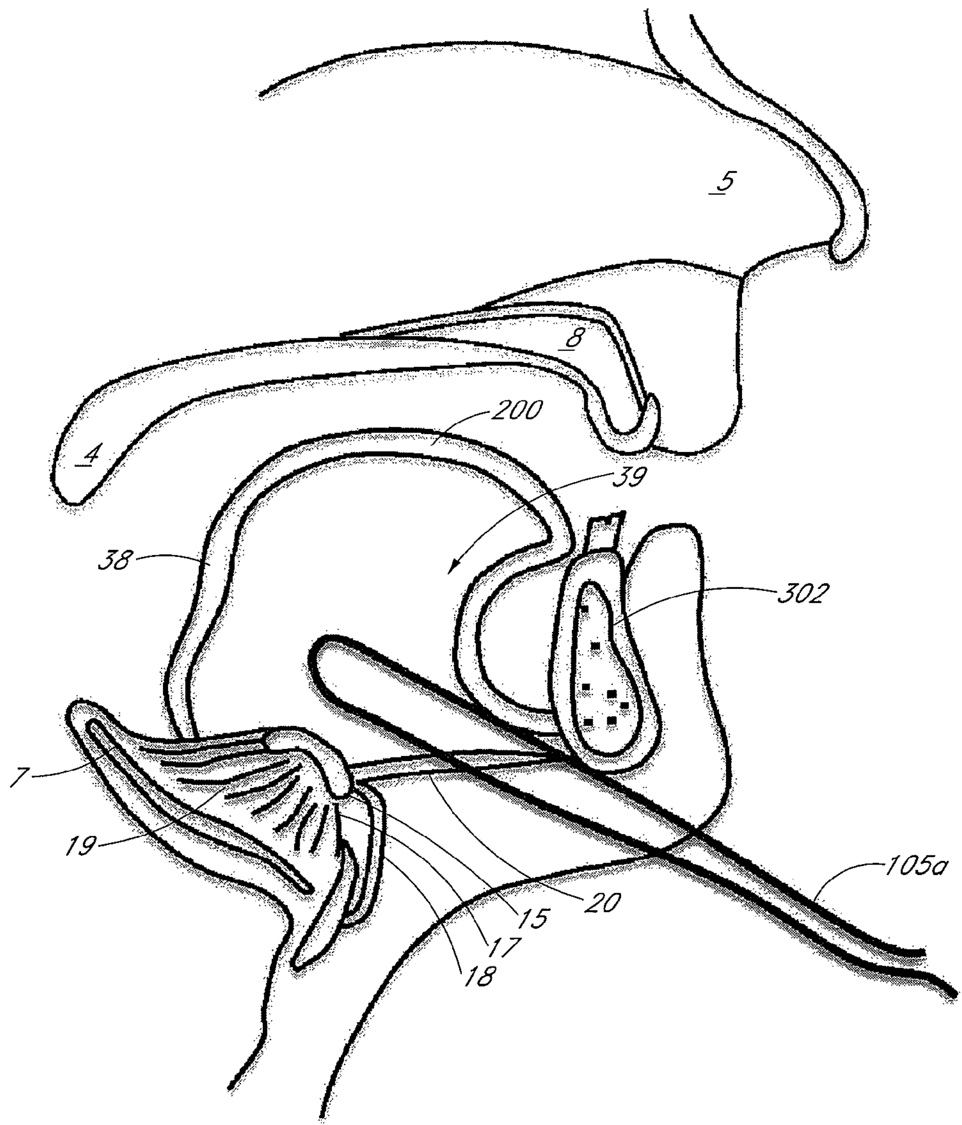

FIG. 15M

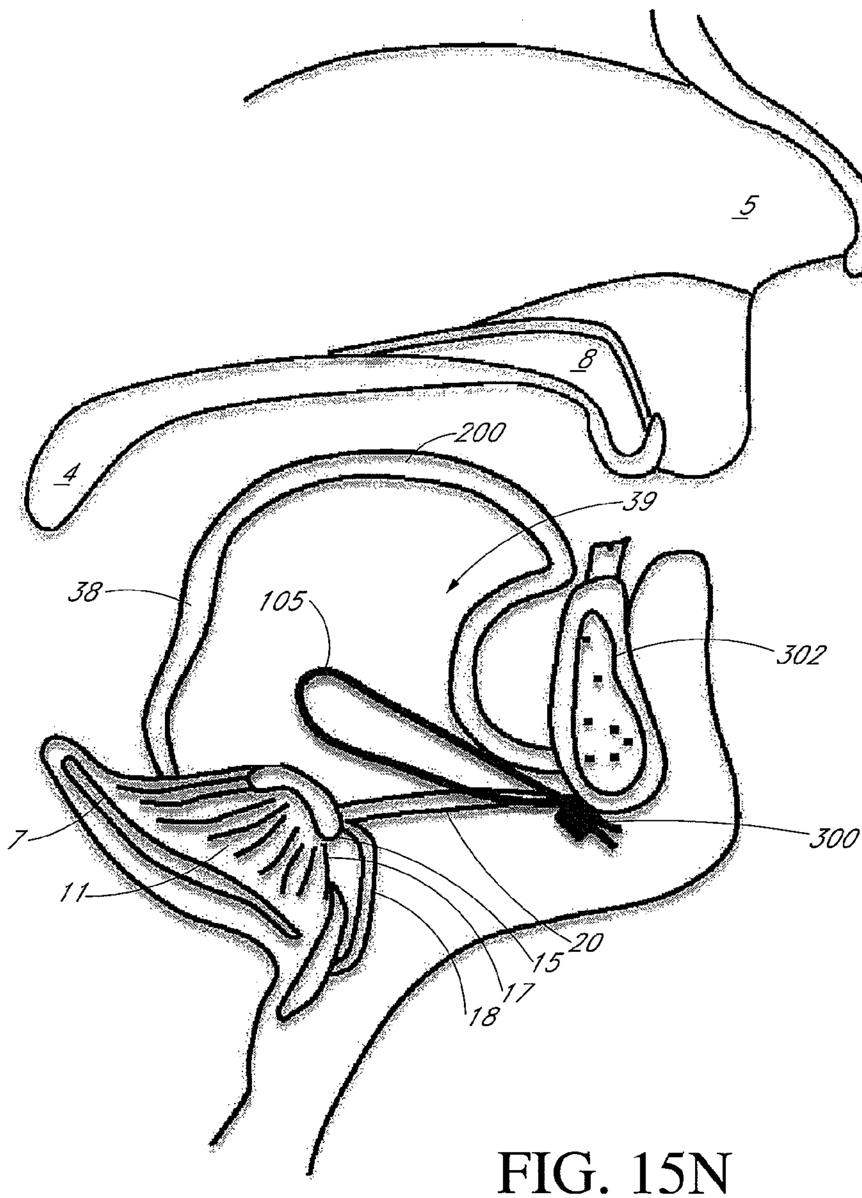

FIG. 15N

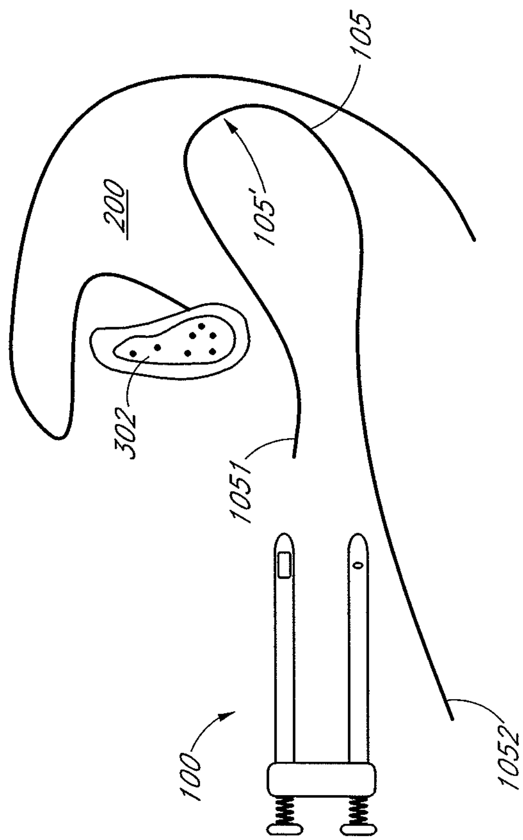

FIG. 15P

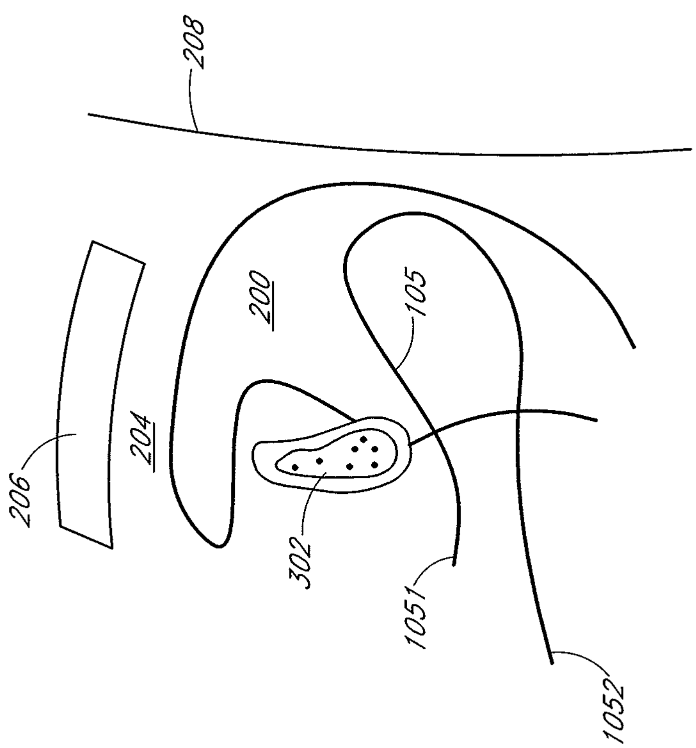

FIG. 15O

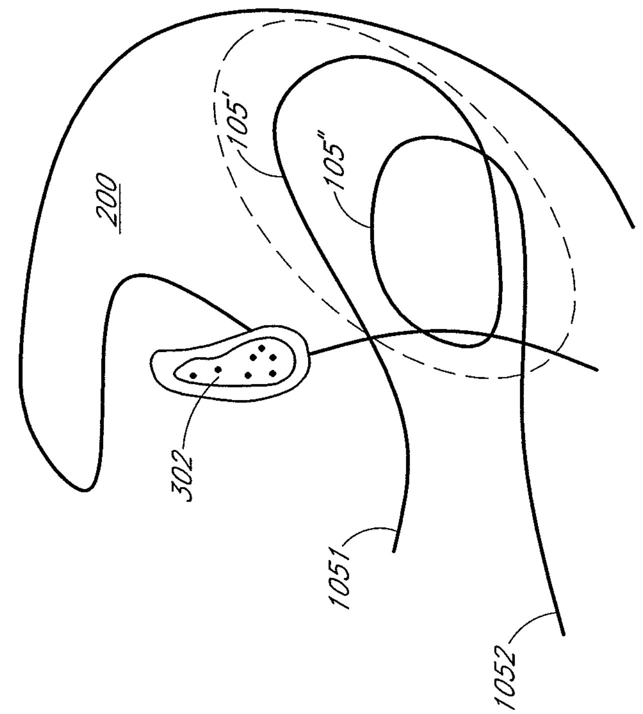

FIG. 15R

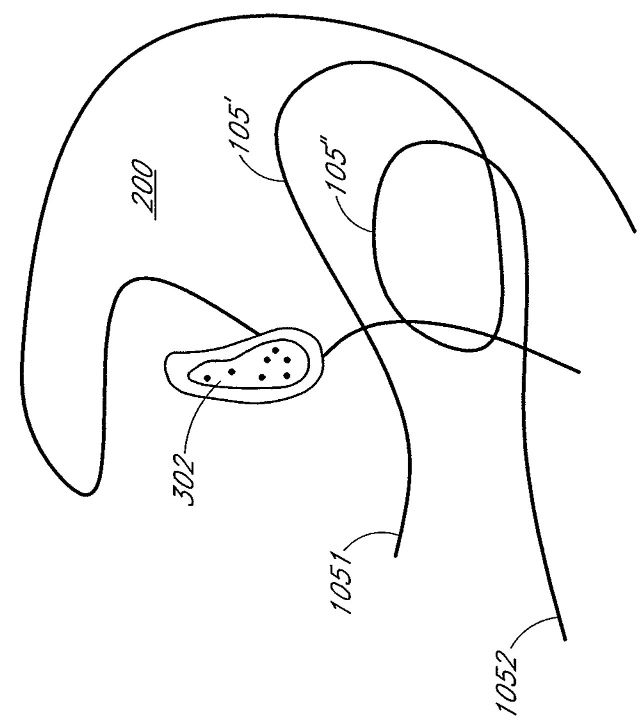

FIG. 15Q

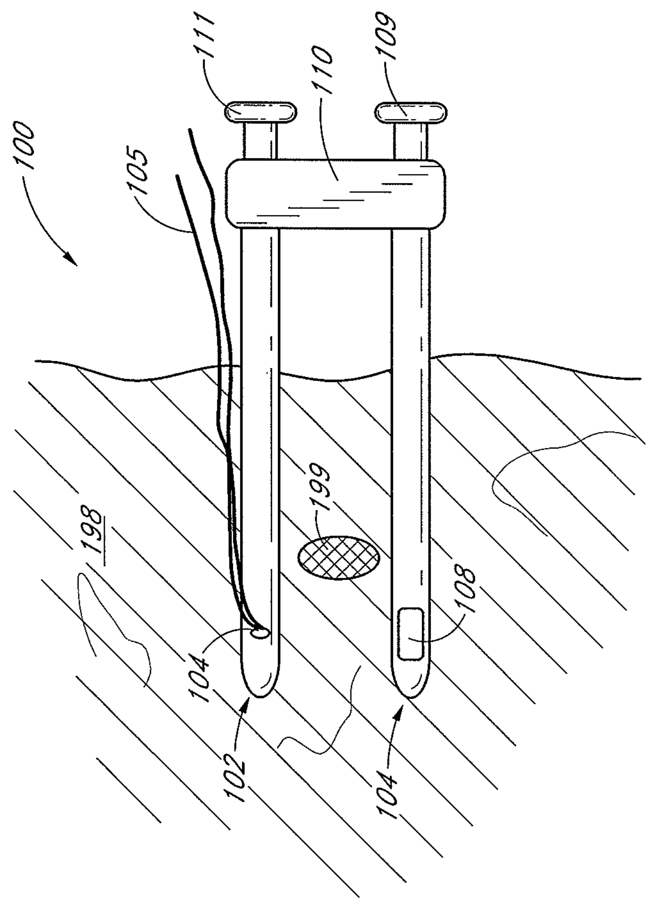

FIG. 15T

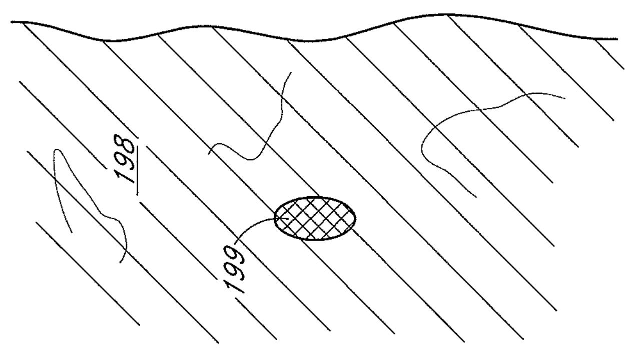

FIG. 15S

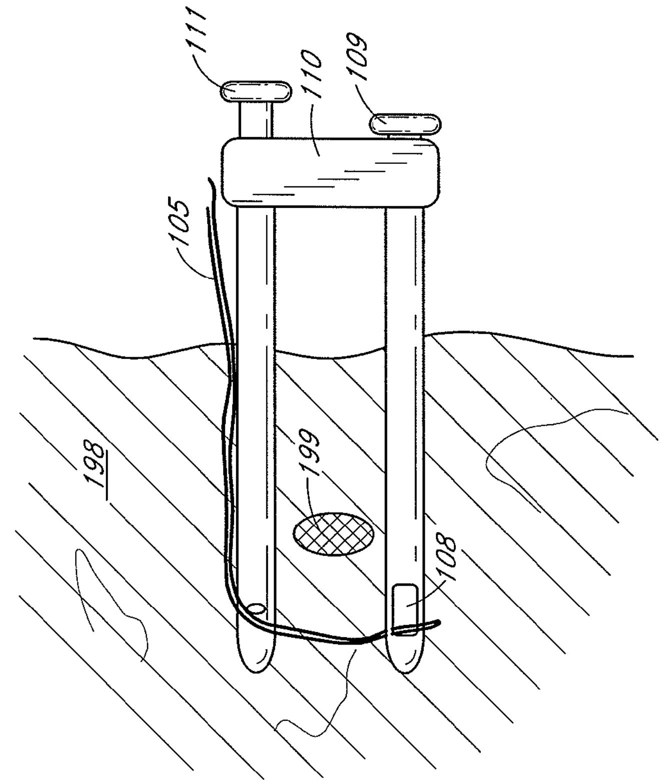

FIG. 15V

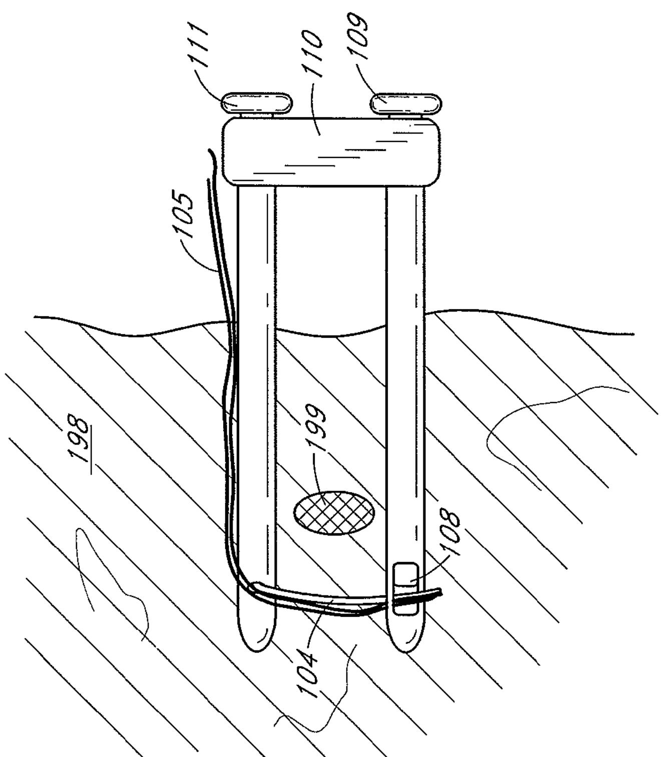

FIG. 15U

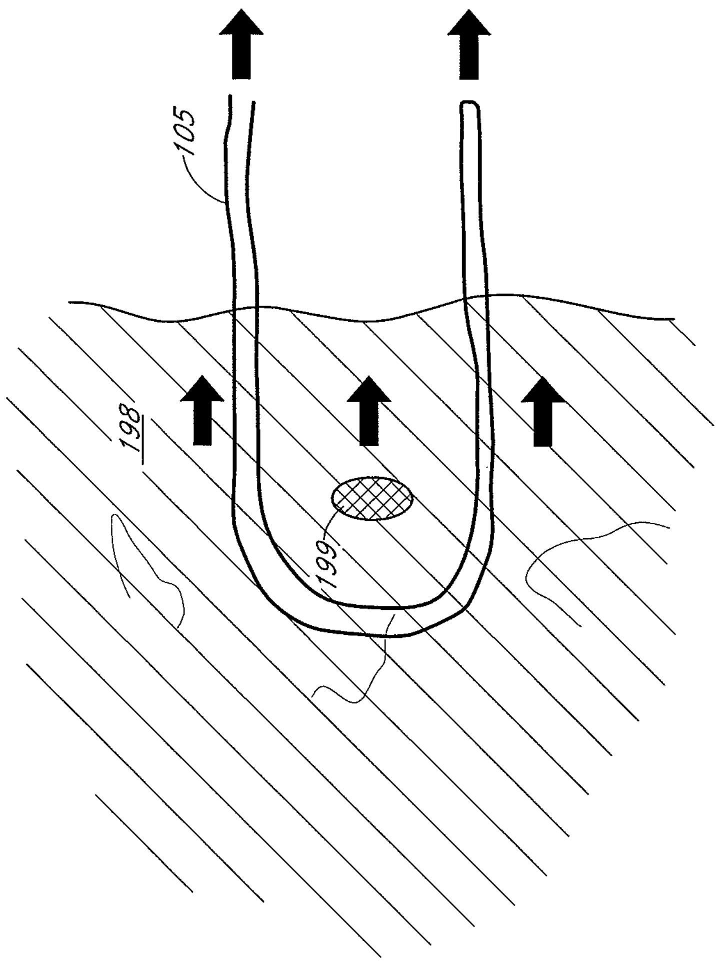

FIG. 15W

TETHER LINE SYSTEMS AND METHODS FOR TONGUE OR OTHER TISSUE SUSPENSION OR COMPRESSION

PRIORITY CLAIM

This application claims priority under 35 U.S.C. §119(e) as a nonprovisional application of U.S. Prov. Pat. App. No. 61/698,457 filed on Sep. 7, 2012, which is hereby incorporated by reference in its entirety.

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates generally to suture passer systems and methods for tissue suspension and tissue compression, and suspension lines, including embodiments with radially enlarged segments.

SUMMARY OF THE INVENTION

Disclosed herein are variable-thickness suspension line for suspending tissue. The suspension lines can include a suture having a first thickness dimension. In some embodiments, the suspension lines also include an elastomer surrounding a portion of the suture and defining a central segment of the suspension line having a second thickness dimension greater than the first thickness dimension. The suspension lines can also include at least one transition zone extending from the central segment of the suspension line to a lateral end of the suspension line, the transition zones having a thickness dimension that tapers from the second thickness dimension to the first thickness dimension.

In some embodiments, the suspension lines include a plurality of transition zones, each transition zone extending from the central segment of the suspension line to respective lateral ends of the suspension line. The elastomer can be overmolded onto the suture. The elastomer can be, for example silicone. The suture can be braided. The suspension line can also include a radiopaque marker operably attached to the suture. The radiopaque marker can be disposed on, for example, the central segment of the suspension line. The suspension line can extend axially along the entire length of the suspension line. The elastomer can be overmolded over a plurality of discontinuous segments of the suture. The central segment of the suspension line can include one or more knots for improving adhesion between the suture and the elastomer. The suspension line could have a rounded, and/or a rectangular cross-section. The central segment can be configured to move between a first axially unstretched configuration and a second axially stretched configuration. In some embodiments, the first thickness dimension can be less than about 0.020 inches. The second thickness dimension can be between about 0.080 inches and about 0.120 inches. An axial length of the central segment can be between about 2 cm and about 3 cm. An axial length of the transition zones can be less than about 1 cm.

Also disclosed herein is a variable-thickness suspension line for suspending tissue. The suspension line can include a tether having a first thickness dimension. The tether can have first and second lateral ends and a central segment. The suspension line can also have an elastomer surrounding and overmolded to the central segment of the tether and defining a central zone of the suspension line, the central zone having a second thickness dimension greater than the first thickness dimension.

In some embodiments, disclosed is a method for performing glossopexy. The method can include providing a variable-thickness suspension line comprising: a suture having a first thickness dimension, the suture extending axially along the suspension line; and an elastomer surrounding and overmolded to a segment of the suture, defining a central segment of the suspension line having a second thickness dimension greater than the first thickness dimension; and wherein areas of the suture not surrounded by the elastomer define lateral ends of the suspension line; passing the suspension line through the base of the tongue to form a loop in the suspension line; and tensioning the suspension line to suspend the tongue. The method can also include securing the suspension line to the mandible.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1**A-**1**C illustrate one embodiment of a cammed bone anchor design that has the advantage of eliminating the need to thread a tether.

FIGS. **2**A-**2**F illustrate an embodiment of a bone anchor design configured to secure a tether.

FIG. **3** illustrates an embodiment of a suspension line that includes a tether, knots or other features to improve adhesion between the molded segment and the tether, a radio-opaque marker, and a molded segment.

FIG. **4** illustrates another embodiment of a suspension line.

FIGS. **5**-**6** illustrate embodiments of suture coil composite suspension lines.

FIG. **7**A-**7**E illustrate various elastic anchor embodiments.

FIGS. **7**F-**7**G illustrate additional elastic embodiments.

FIGS. **8**A-**8**D illustrate tethers including stretch elements that can provide limited compliance to allow for easier swallowing while still providing suspension for sleep apnea resolution.

In some embodiments, as illustrated in FIGS. **9**A-**9**B, the tether can include mechanical elements that can be drops of adhesive that wick into structures of, e.g., ribbon or impregnated silicone, that may be essentially localized stiff sections.

FIG. **10** illustrates an additional suspension line embodiment.

FIG. **11** illustrates another suspension line embodiment.

FIG. **12** illustrates another embodiment of a suspension line.

FIGS. **13**A-**13**B illustrate a suture loop placed in the tongue having a suture lock mechanism.

FIG. **14** illustrates a method of using one embodiment of a suture passer system to create a suture loop having a vertical orientation.

FIG. **15** illustrates a method of using one embodiment of a suture passer system to introduce serial spaced-apart or overlapping multiple suture loops into tissue.

FIGS. **15**A-**15**D illustrate a method of delivering a plurality of suture loops into tissue having a common midline axis, according to one embodiment of the invention.

FIG. **15**E illustrates a method of accessing the tongue with pharyngeal anatomy, according to one embodiment of the invention.

FIGS. **15**F-**15**N illustrate one embodiment of a method to create a suture loop in the base of the tongue.

FIGS. **15**O-**15**R illustrate one embodiment of a method to create a plurality of suture loops in tissue.

FIGS. **15S-15W** illustrate a method of passing a suture loop around a structure other than tissue, according to one embodiment of the invention.

DETAILED DESCRIPTION

This application incorporates by reference in its entirety U.S. Pat. Pub. No. 2011/0245850 A1 to van der Burg et al. Embodiments of elements disclosed herein including bone anchors, suspension lines, and/or suture lock mechanisms can be used or modified for use with systems, apparatuses, and methods, including suture passers for tongue and other tissue compression as described in U.S. Pat. Pub. No. 2011/0245850 A1. The term "suture" as used herein, unless otherwise specified or limited, is intended to have its ordinary meaning and is also intended to include all structures, including any of the aforementioned or later-described examples, that can be passed through tissue using the devices described herein. One example of tissue that can be suspended or compressed is the genioglossus muscle of the tongue. Such a system could be useful in treating a wide range of conditions, including, for example, obstructive sleep apnea. Other non-limiting examples of tissues that can be suspended or compressed include using systems and methods as described herein include facial soft tissue such as in the forehead, brow, mid face, jowls, lateral face, lips, eyelids, nose, and neck to treat wrinkles or asymmetry; the breast and/or nipple-areola complex to treat ptosis; the bladder, such as the bladder neck to treat incontinence or a cystocele; the uterus or vagina to treat prolapse; or muscles, tendons, and/or ligaments to treat a partial or complete tear. The suture passer system could be used to ligate blood vessels such as arteries or veins that are not easily accessible without a surgical access procedure. Other non-limiting examples of anatomical structures that can be suspended other luminal structures such as a lymphatic, fallopian tube, bile duct, or ureter; or an organ such as, for example, the esophagus, stomach, small intestine, colon, rectum, bladder, uterus, vagina, eye, liver, lung, gallbladder, spleen, pancreas, or kidney. The suture passer can also be used to suspend other structures located within tissue, such as bone, as will be described further below.

FIGS. **1A-1C** illustrate one embodiment of a "threadedless" cammed bone anchor design that has the advantage of eliminating the need to thread a tether, e.g., a suture **2102** to be anchored through the bone anchor eyelet. This can be accomplished by eliminating a portion **2110** of the top of the bone anchor insert piece **2112** and also creating appropriate grooves **2114** in the outside wall of the bone anchor body **2104**. The suture **2102**, bone anchor body **2104**, and insert **2112** are illustrated, as well as insert loading pin **2108**. FIG. **1**A illustrates a vertical cross-sectional view of the cammed design in the open state. FIG. **1**B illustrates the insert rotated 90-180 degrees with respect to FIG. **1**A, with the cammed anchor in the closed position. FIG. **1**C is a top view that also illustrates slots **2114** in the body for laying in and loading suture **2102**; the insert **2112**; and a hex engagement **2116**.

FIGS. **2A-2**F illustrate an embodiment of a bone anchor design **200 0** configured to secure a tether. A tether is passed through the eyelet **206** in the open configuration, as illustrated in the top view (FIG. **2**A), a side view (FIG. **2**B), and a side partial sectional view (FIG. **2**C). As illustrated in FIG. **2**A, an inner member or core **202** is moveable/rotatable with respect to the outer member **204**. Placing the bone anchor insert in the closed configuration, as illustrated in the top view (FIG. **2**D), a side view (FIG. **2**E), and a side partial sectional view (FIG. **2**F) secures the tether between surfaces within the bone anchor. As illustrated, when the core **202** is rotated, a tortuous path results in a small path/gap **208** between the outer diameter of the core and the inner diameter of the outer member which pinches and locks the suture in place.

FIG. **3** illustrates an embodiment of a suspension line **300** that includes a tether **301**, knots **1302** or other features to improve adhesion between the molded segment **304** and the tether **301**, a radio-opaque marker **303**, and molded segment **304**. The tether **301**, which can be a suture, forms a backbone of the suspension line **300** and in some embodiments may be continuous underneath the overmolded segment **304** or discontinuous with a molded segment **304** molded over a plurality of discrete suture segments. Also shown is an axial length **312** of the suspension line **300**. The overmolded segment **304** could have a length **310** that is somewhat less than the length **312** of the total suspension line **300**, and include a main body length **306** with a first diameter, and a tapered segment **308** having a second diameter that tapers, e.g., gradually from the central main body length **306** to first and second lateral ends **314**, **314'** of the suspension line **300**, the second diameter being less than the first diameter.

FIG. **4** illustrates another embodiment of a suspension line **400**, somewhat similar to FIG. **3**, showing a suture backbone **402** that can be braided, and a central molded segment **408** that may be made of a suitable material such as silicone, and have a cylindrical cross-section that tapers laterally. A radiopaque marker **406** can be present on the suspension line **400**, such as under the silicone overmolded segment **408**. The braided suture backbone **402** can have one or more knots **404** that can advantageously help to maintain the position of the marker **406** and increase adhesion with the molded material.

FIGS. **5-6** illustrate embodiments of "suture coil" composite suspension lines **500** where a first suture **506**, e.g., a #2 suture continuously runs the length of the suspension line and a second larger suture **502**, such as a #9 suture is used to bulk up the middle section of the suspension line. As illustrated in FIG. **5**, the #2 suture **506** exits from the #9 suture **502** and is wrapped around the #9 suture **502**. The #2 suture **506** is threaded down the midline of the #9 suture **502**. The tips **504** of the #9 suture **502** can be melted and shaped to provide a tapered transition and also to provide anchoring of the #2 suture **506**. In some embodiments, the #2 suture **506** may pull through the #9 braid **502** if it were not melted into a solid mass at the tips **504**. The tapered section **504** also provides a transition from the smaller #2 suture **506** diameter up to the bulked up and coiled midsection **502**. This transition **504** in some embodiments helps the suspension line **500** be easily passed through a path through tissue and prevent tissue ingrowth into parts of the structure.

In some embodiments, advantages of this design include providing a continuous first suture with a first, relatively smaller diameter, e.g., a #2 suture to ensure the strength of the loop and eliminating junctions that may reduce reliability. Also, the ability to securely "bulk up" a suspension line can be advantageous. Furthermore, the bulked-up configurations may be coated in silicone or another layer to further smooth transitions. The larger suture may also be glued or otherwise attached to the underlying suture. As illustrated in the suture coil **600** embodiment of FIG. **6**, the #2 suture **602** is threaded all of the way through the midline of the larger #9 suture **604**. Melted and molded tips **606** as indicated provide a transition. Similar to FIG. **5**, the #2 suture **602** is threaded all of the way through the midline of the larger #9 suture **604**. Knots **608** or other means can secure the #9 suture **604** along its length.

FIG. **7**A-**7**E illustrate various elastic anchor embodiments. As illustrated in FIG. **7**A, an elastic element **1702** in the tongue **200** operably connected to a suture line **1700**, which in turn can be connected to a structure such as the mandible **302**. The elastic element **1702** can stretch under load to accommodate swallowing/speech. As illustrated in FIG. **7**B, a suture **1700** can have an unstretched portion **1701** molded into an elastomer **1703**, forming elastic element **1702**. FIGS. **7**C and **7**D illustrate the embodiment of FIG. **7**B partially and fully stretched, respectively; the suture **1700** limiting the amount of stretch. FIG. **7**E illustrates a schematic graph of force vs. displacement, also showing the displacement limit of the suture.

FIGS. **7**F-**7**G illustrate additional elastic suture embodiments. As shown in FIG. **7**F, axially compressing a suture **1721** made of a woven-braided material, e.g., in the direction of arrows **1720**, then impregnating with an elastomer can give a similar effect of limited elasticity. The suture **1721** can include an expanded region **1722** with elastomer impregnated between suture **1721** fibers. When stretched, the elastomer will elongate and return to the compressed shape after the stretch force is released. FIG. **7**G illustrates a suture **1730** having a central coiled section **1731** surrounded by an elastomer **1732**.

In some embodiments, the stretch element can provide limited compliance to allow for easier swallowing while still providing suspension for sleep apnea resolution. Some embodiments including limited compliance stretch elements are illustrated in FIGS. **8**A-D. As illustrated in FIG. **8**A, the suspension line **800** includes a ribbon **802** with a central portion **803** including an elastomer **804**, and can be stretched as shown in FIG. **8**B an axial length X greater than the unstretched length **803**. As shown in FIG. **8**C, a suspension line **810** can include a woven ribbon **812** with an expanded weave central portion **814**, and an elastomer **816** operably connected to, such as impregnated into the weave **814**. FIG. **8**D illustrates the suspension line **810** in an axially stretched configuration, showing the weave at the limit of axial stretch.

In some embodiments, as illustrated in FIG. **9**A, the tether **900** can include mechanical elements **902** that can be, for example, drops of adhesive that wick into structures of, e.g., ribbon **904** or impregnated silicone, that may be essentially localized stiff sections. The mechanical elements **902** can also be larger than the ribbon **904** in some embodiments. Spacing the elements a distance X is large enough that flexibility is maintained so a ribbon **904** can curve around a bend, but also small enough to prevent twisting and collapse of the ribbon **904**. It may be desirable to have stretch elements **924** in an otherwise non-compliant suspension ribbon **922**, as illustrated in the suspension line **920** shown in FIG. **9**B.

FIG. **10** illustrates an additional suspension line **1000** embodiment. There is a perception by some surgeons that a small diameter suture (e.g., #1 or #2 USP, about 0.5 mm) could potentially migrate through the tongue when the suture has tension applied acting in the anterior direction. One means to address this perception is to place a larger suture in the tongue such that a given applied tension results in a lower pressure against the genioglossus muscle because of the larger area projection of the suture. In some embodiments, simply using a larger suture may not be ideal because of the interface between the suture and the bone anchor that attaches the suture to bone. A larger suture will require a larger bone anchor. A suspension line **1000** with small diameter/thickness tails **1002** with an intermediary large diameter/thickness segment **1004** is preferred in some embodiments.

FIG. **11** illustrates another suspension line embodiment **1100**. The small diameter tails **1101** can be standard braided or monofilament suture lengths. The larger diameter section **1102** can be created by, for example:

- bulking up the braided suture by inserting a plastic, metal, or other component into the braiding process such that the suture fibers braid around the inserted body.
- Bulking up a monofilament can be accomplished by adding additional material on the main spine and/or intermittently changing the drawing parameters of the monofilament to allow for material to accumulate at specific locations.
- Adding more fibers to the braid or altering the braid in some way to allow the diameter of suture to grow at defined locations.

The cross-section of the suspension line **1100** along its length can be substantially round, oval, or other shapes in some embodiments. In some embodiments, there can be a transition region **1104** on either/both sides of the large diameter section **1102**. The small diameter suture **1101** may or may not need to be continuous throughout the length of the suspension line **1100**.

FIG. **12** illustrates another embodiment of a suspension line **1200**. The small diameter tails **1201** of the line **1200** can be standard braided suture or monofilament suture for example. A silicone (or similar material) hammock **1202** can be molded over the suture **1204** to create a large section **1203**. The hammock **1202** can have a substantially round or rectangular profile with a thickness and width. In some embodiments, the thickness could be less than the width in order to have a preferred bending direction once the tails of the suture are tensioned. In some embodiments, the small diameter suture **1204** could be USP #2, or about 0.020" or less in diameter. In some embodiments, the large diameter/thick sections **1202** could be between about 0.080" to 0.120", or 0.020" to 0.030"×0.080" to 0.120" as illustrated. In some embodiments, the lengths of the large diameter/thick sections **1202** could be between about 2 cm and about 3 cm. The length of the taper **1205** could be, for example, less than 1 cm, or less than 0.5 cm. In some embodiments, the small diameter suture **1204** could be USP #3, or about 0.024" or less in diameter. In some embodiments, the large diameter/thick sections **1202** could be between about 0.030" to 0.200", or 0.020" to 0.030"×0.030" to 0.200", or have a diameter that it at least about 20%, 30%, 40%, 50%, 60%, 75%, 100%, 125%, 150%, 200%, or more larger than that of the small diameter suture **1204**. In some embodiments, the lengths of the large diameter/thick sections **1202** could be between about 1 cm and about 5 cm. The length of the taper **1205** on either side of the largest diameter/thickest section **1202** could be up to about 20%, 30%, 40%, or 50% of the length of the entire large diameter/thick section **1202**.

The surface of any of the disclosed suspension lines may be mechanically, chemically, or otherwise modified to improve adhesion with, for example, muscle cells and other tissues of the genioglossus. Mechanical modifications create improved adhesion by modifying the surface texture of the implant and may be achieved as part of the manufacturing process and may involve the removal of material from, or the addition of material to the surface of the implant. Chemical adhesion may be achieved through the incorporation of chemical (including biological) compounds into the surface or the bulk material or materials that makes up the implant in order to improve the affinity between cellular components and the implant. Compounds may include, but are not limited to proteins, peptides, antibodies, growth factors, or other molecules which create an affinity for cellular or tissue components.

FIGS. **13**A-**13**B illustrate a suture loop **1300** placed in the tongue **200** having a suture lock mechanism **1302**. If it is not desirable to place bone anchors in the mandible, then a potentially less invasive and effective implant could be to form a complete loop within the tongue base which may then be tensioned to compress the tissue of the tongue **200**. As illustrated in the embodiment shown in FIG. **13**A, a simple suture loop **1300** is placed then tensioned to compress the tongue **200**. A suture lock mechanism **1302** can maintain the desired tension. As illustrated in the embodiment of FIG. **13**B, a "hammocked" suture loop **1306** with broader ends **1308** relative to the central sections **1310** are placed and then tensioned to compress the tissues of the tongue **200**. Multiple loops **1300** can be placed and tensioned to better control advancement of the tongue **200**. Also, elastic suture material may be used in order to provide normal tongue function while preventing tongue base collapse that cause apnea and hypopnea. The suspension lock mechanism **1302** is meant to be knotless in some embodiments and to allow for changes in tension if desired over time.

In some embodiments, as illustrated in FIG. **14**, the suture passer **100** can be inserted into the tissue **200** in a generally vertical orientation, that is, the straight-line distance between the distal tip of the first elongate shaft **102** and the distal tip of the second elongate shaft **106** falls along a generally superior-inferior axis.

In some embodiments, as illustrated in FIG. **15**, a plurality of vertically-oriented suture loops **105**, such as at least 2, 3, 4, 5, 6, or more suture loops can be created in the tissue **200** by advancing the suture passer **100** in a generally vertical orientation as in FIG. **14**, and repeating steps. In some embodiments, the suture loops **105** could be within about 10 degrees of the vertical axis. However, in other embodiments, the suture loops **105** could be within about 75, 60, 45, 40, 35, 30, 25, 20, or less degrees of the vertical axis. This provides more localized control of tissue suspension, depending on the desired clinical result. In some embodiments, a combination of horizontally-oriented and vertically-oriented suture loops can be used, or just horizontally-oriented suture loops. In some tongue embodiments, the distance between suture loops **105** could be irregular or regular. The distance between the midlines of the suture loops **105** could be, for example, between about 0.1 cm and about 3 cm. The multiple suture loops **105** may also have the same or differing orientations within the tissue **200**. In some instances where additional suture strength is required at a single location within tissue, the multiple suture loops may share a midline axis, as illustrated in FIGS. **15**A-**15**D, but have loops oriented differently (from 0 to +90 degrees) from each other. FIG. **15**A illustrates schematically a first suture pass **105***a* through tissue, while FIG. **15**B illustrates both a first suture pass **105***a* and a second suture pass **105***b* sharing a common midline axis 105×. FIG. **15**C illustrates an end view of FIG. **15**B, while FIG. **15**D illustrates a side view of FIG. **15**B.

Substantially vertical suture loop(s) placed at the midline of the tongue base may have additional advantageous as therapy for preventing an apnea event. First, by acting on the midline, the suture loop is less likely to affect the lateral walls of the pharynx. Second, if there is collapse of the tongue base against the posterior wall of the pharynx, the tissue may be "tented" at the midline, maintaining at least some pathway for air and avoiding complete obstruction of the pharynx. This is similar to the effect seen with a midline glossectomy.

Tissue **200** may be suspended by securing the free ends of suture loop(s) **105** to a structure such as a bone anchor (e.g., implanted in the mandible or hyoid bone) or other body structure outside the tissue **200**. Other body structures in which the suture loop could be attached to include, for example, the hyoid bone or the soft palate. Alternatively, the free ends of suture may be tied in a knot or otherwise secured to suspend the tissue **200**.

When tongue suspension is desired, the tongue could be accessed via the oral cavity. In some instances, embodiments of the tongue suspension system can be implanted through an antero-inferior access site of the mandible. Implantation of the system that avoids the transoral route may improve infection rates that occur with other tongue related devices and procedures.

A description of pharyngeal anatomy and a method for suspending the tongue will now be described. FIG. **15**E is a sagittal view of the structures that comprise the pharyngeal airway and may be involved in obstructive sleep apnea. The pharynx is divided, from superior to inferior, into the nasopharynx **1**, the oropharynx **2** and the hypopharynx **3**. The nasopharynx **1** is a less common source of obstruction in OSA. The nasopharynx is the portion of the pharynx above the soft palate **4**. In the nasopharynx, a deviated nasal septum **5** or enlarged nasal turbinates **6** may occasionally contribute to upper airway resistance or blockage. Only rarely, a nasal mass, such as a polyp, cyst or tumor may be a source of obstruction.

The oropharynx **2** comprises structures from the soft palate **4** to the upper border of the epiglottis **7** and includes the hard palate **8**, tongue **200**, tonsils **10**, palatoglossal arch **11**, the posterior pharyngeal wall **12** and the mandible **302**. The mandible typically has a bone thickness of about 5 mm to about 10 mm anteriorly with similar thicknesses laterally. An obstruction in the oropharynx **2** may result when the tongue **200** is displaced posteriorly during sleep as a consequence of reduced muscle activity during REM sleep. The displaced tongue **200** may push the soft palate **4** posteriorly and may seal off the nasopharynx **1** from the oropharynx **2**. The tongue **200** may also contact the posterior pharyngeal wall **12**, which causes further airway obstruction.

The hypopharynx **3** comprises the region from the upper border of the epiglottis **7** to the inferior border of the cricoid cartilage **14**. The hypopharynx **3** further comprises the hyoid bone **15**, a U-shaped, free floating bone that does not articulate with any other bone. The hyoid bone **15** is attached to surrounding structures by various muscles and connective tissues. The hyoid bone **15** lies inferior to the tongue **200** and superior to the thyroid cartilage **16**. A thyrohyoid membrane **17** and a thyrohyoid muscle **18** attaches to the inferior border of the hyoid **15** and the superior border of the thyroid cartilage **16**. The epiglottis **7** is infero-posterior to the hyoid bone **15** and attaches to the hyoid bone by a median hyoepiglottic ligament **19**. The hyoid bone attaches anteriorly to the infero-posterior aspect of the mandible **302** by the geniohyoid muscle **20**.

Methods of treating a condition of an airway will now be described. For example, the method can comprise creating a first pathway within the tongue **200** without passing through the mucosa, and creating a second pathway within the tongue **200**. For example, FIG. **15**E depicts one embodiment of the invention where the suture passer **700** is inserted into the tongue **200** through an insertion site inferior to the mandible **302**, which could be but is not necessarily about the anterior portion of the mandible **302**. In other embodiments, the implantation pathway may originate from a location anterior or lateral to the mandible **302**, and in still other embodiments, may also pass through the mandible **302**. The suture passer **700** may be inserted percutaneously to create the first pathway and the second pathway. Prior to insertion of the suture passer **700**, optionally a guide catheter, needle, or other piercing delivery tool known in the art could be initially placed, and followed by a guidewire. The method can further comprise passing a flexible elongate member (e.g., suture loop) extending through the first pathway through the tongue tissue from the first pathway to the second pathway. In some instances, the distal portion of the suture loop is positioned about the base of the tongue, which is the portion of the tongue posterior to the circumvallate papillae (not shown), but other locations within the tongue **200**, such as the anterior portion **39**, may also be used. For example, the loop portion of the suture loop may also be positioned in the dorsal region **38** of the tongue **200**. When the suture loop is withdrawn from the second pathway, the suture loop forms a looped path through the tongue **200**.

In FIG. **15**E, the embodiment of the suture passer **700** can have a dual-shaft configuration with a single actuator control **701** at a proximal end. The suture passer **700** also has a body **703** housing different mechanical components, including secondary control **711** along a sidewall of the body **703**. Suture passer **700** may also include finger grips **713** extending from opposite sidewalls of the body **703**. A first elongate shaft **702** and a second elongate shaft **706** extend distally from the body **703**.

Steps as illustrated in FIGS. **15**F-**15**J can be described in connection with formation of a suture loop via use of a suture passer completely within the tissue **200**. A suture **105** is passed through the base of the tongue **200** using, for example, a suture passer **700** or any other embodiment of a suture passer as described elsewhere. FIGS. **15**F-**15**N show a procedure and sequential steps for anterior suspension of the tongue **200**. As illustrated in FIG. **15**F, the suture passer **700** is advanced distally into tissue of the base of the tongue **200** without passing through the tongue mucosa. The suture passer **700** can be inserted into the tongue **200** at an angle to the superior-inferior axis. The first elongate shaft **702** may be positioned inferiorly relative to the second elongate shaft **706** as the suture passer **700** is delivered distally into the base of the tongue **200**. Next, shown in FIG. **15**G, a flexible needle **704** carrying the suture **105** is advanced through a window of a suture-capturing element **708**. As illustrated in FIG. **15**H, the flexible needle **704** is retracted back into the first elongate shaft **702**, leaving the suture **105** in the capture window, such as when a movable panel of the second elongate shaft **706** slides against an end of the window, closing the window. As shown in FIGS. **15**I-**15**J, the suture passer **700** is withdrawn to leave behind the suture **105** in the tissue **200**.

When suspending the tongue and advancing the genioglossus anteriorly, the precise placement and tensioning of an implant can avoid potentially increasing potential lateral collapse of the pharynx. Furthermore, tongue suspension using the methods and devices as disclosed herein can be advantageous as the procedure, in at least some embodiments, can be fully reversible by simply removing the suture(s).

In FIGS. **15**K-**15**N, a method of inserting another structure or tension element, such as a suture within the tongue **200** is provided. Upon release of the suture **105** from the suture passer **100**, the suture **105** may include a closed end **105***b* and free ends **105***c*. The suture **105***a* may pass through and be secured to the closed end **105***b* of the suture **105**. When the suture **105** is pulled from the free ends **105***c*, the suture **105***a* is drawn into the tongue **200** and toward the dorsal region **38**. The suture **105***a* positioned in the tongue **200** can add strength and greater tension, based at least in part on its size and/or material properties, so as to provide additional tissue control. In some embodiments, the suture **105***a* is a tension element that is thicker than the suture **105**. Moreover, the first suture **105** can be a guide suture or a suture loop having a width that is less than 90%, 80%, 70%, 60%, 50%, or less of the tension element **105***a*. The tension element **105***a* can be advanced toward the anterior portion **39** to further suspend the tongue **200** and advance the genioglossus anteriorly. The tension element **105***a* can be secured via a bone anchor **300**.

As illustrated in FIG. **15**N, a bone anchor **300** could be implanted near the midline of the mandible **302** as shown, and the free ends of the tether **105***a* then attached thereto. In the method shown in FIGS. **15**F-**15**N, the free ends of the **105***a* do not need to be pre-attached to the bone anchor **300**, allowing for additional convenience and ease in creating the appropriate tension in the suture loop. The bone anchor **300**, when inserted into the mandible **302** is typically located about an anterior portion of the mandible **302** and may involve the external, internal or inferior surface of the mandible **302** or a combination of these surfaces. In some embodiments, a lateral or anterolateral location about the mandible **302** may be used.

With reference to FIGS. **15**O-**15**R, a method of passing multiple suture loops through the tongue, such as the posterior portion of the tongue, is provided. FIG. **15**O illustrates a schematic sagittal cross-sectional view of a tongue **200**. Above the oral cavity **204** is the palate **206**, and posterior to the tongue **200** is a pharyngeal wall **208**. The tongue **200** abuts the mandible **302** anteriorly.

Still referring to FIG. **15**O, using a suture passer **100**, which can be, for example, as previously described, a first suture loop **105'** having a first end **1051** and a second end **1052** is passed through the tongue **200** in a generally anterior-to-posterior direction. However, the first end **1052** of the suture loop **105'** is reintroduced onto the suture passer as illustrated in FIG. **15**P and is again passed into the tongue **200**. In other embodiments, a second discrete suture could be passed instead of the first end of the first suture simply reintroduced onto the suture passer. In some embodiments, one or more of suture loops **105'**, **105"** may be vertically oriented as described in FIG. **15**, or oriented in a horizontal plane, or at other various angles as previously described.

In FIG. **15**Q, a second suture loop **105"** is passed through the tongue **200** to provide additional tissue control. As with the first suture loop **105'**, the second suture loop **105"** does not pass all the way through the tongue posteriorly. In some embodiments, the second suture loop **105"** passes along substantially the same path as or near the same path as the first suture loop **105'**, or through different paths, such as described, for example, in connection with FIGS. **15**A-**15**D above. Additionally, at least 3, 4, 5, 6, 7, 8, or more suture loops can be created in the tongue **200** by repeating the suture passing procedure to provide even more anchoring control.

In FIG. **15**R, a tension force (T) is applied to the free ends **1051**, **1052** of the suture loops **105'**, **105"** to effectively compress and/or shorten the anterior-posterior dimensions of the tongue **200**. The free ends **1051**, **1052** could then be tied within the tongue **200**, obviating the need for a bone anchor, or alternatively secured to a surrounding structure such as the mandible **302** and/or hyoid bone. In some embodiments, the tongue **200** may be compressed in the anterior-posterior direction by at least about 2%, 3%, 5%, 10%, 20%, 30%, or more. In the embodiment where the suture **105** is secured to the mandible **302** or to a bone anchor in the mandible, this single surgical technique provides two types of therapy to the tongue **200**. The outer suture loop **105'** (whose loop segments are closest to the end of the suture) acts to suspend the tongue **200** as described previously. The inner suture loop **105"** (whose loop segment is nearest the midline of the suture) acts to compress the tissue within the tongue **200**. This combined therapy from a single suture **105** may be particularly advantageous in patients with overly large tongues or with obese patients whose tongues have additional fatty deposits within the genioglossus. As a result, the procedure can increase the size of the oral cavity **204** by advancing the tongue **200** forward, which could relieve airway obstruction.

As noted, systems and methods described herein can be used to suspend any biological structure such as tissue. FIGS. **15S-15W** schematically illustrate a method of using a suture passer to suspend an anatomical structure that may not be tissue. As previously mentioned, the anatomical structure could be, for example, a tubular structure such as a blood vessel, or various other structures disclosed elsewhere herein. FIG. **15S** schematically illustrates a cross-section of a structure **199** spaced apart from a tissue surface **198**. As shown in FIG. **15T**, the suture passer **100** is deployed, such as into tissue **198**, and positioned to pass the suture **105** around the structure **199**. The suture **105** is then passed around structure **199** from suture-passing element (e.g., needle **104**) to suture-receiving element **108** (such as a snare or capture window), as illustrated in FIG. **15U**. The suture-passing element **104** is then retracted, and the suture-receiving element **108** transformed to capture the suture **105**, as illustrated in FIG. **15V**. The suture passer **100** is then retracted and removed as shown in FIG. **15W**, and tension formed on the suture loop **105**. The structure **199** can then be suspended to an anchoring structure (not shown) such as, for example, a bone anchor, tissue anchor, or tied in a loop within the tissue **198**.

It is contemplated that various combinations or subcombinations of the specific features and aspects of the embodiments disclosed above may be made and still fall within one or more of the inventions. Further, the disclosure herein of any particular feature, aspect, method, property, characteristic, quality, attribute, element, or the like in connection with an embodiment can be used in all other embodiments set forth herein. Accordingly, it should be understood that various features and aspects of the disclosed embodiments can be combined with or substituted for one another in order to form varying modes of the disclosed inventions. Thus, it is intended that the scope of the present inventions herein disclosed should not be limited by the particular disclosed embodiments described above. Moreover, while the invention is susceptible to various modifications, and alternative forms, specific examples thereof have been shown in the drawings and are herein described in detail. It should be understood, however, that the invention is not to be limited to the particular forms or methods disclosed, but to the contrary, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the various embodiments described and the appended claims. Any methods disclosed herein need not be performed in the order recited. The methods disclosed herein include certain actions taken by a practitioner; however, they can also include any third-party instruction of those actions, either expressly or by implication. For example, actions such as "passing a suspension line through the base of the tongue" include "instructing the passing of a suspension line through the base of the tongue." The ranges disclosed herein also encompass any and all overlap, sub-ranges, and combinations thereof. Language such as "up to," "at least," "greater than," "less than," "between," and the like includes the number recited. Numbers preceded by a term such as "approximately", "about", and "substantially" as used herein include the recited numbers, and also represent an amount close to the stated amount that still performs a desired function or achieves a desired result. For example, the terms "approximately", "about", and "substantially" may refer to an amount that is within less than 10% of, within less than 5% of, within less than 1% of, within less than 0.1% of, and within less than 0.01% of the stated amount.

What is claimed is:

1. A variable-thickness suspension line for suspending tissue, comprising:

a suture having a first thickness dimension; and

an elastomer coating a portion of the suture and defining a central segment of the suspension line having a second thickness dimension greater than the first thickness dimension, and at least one transition zone extending from the central segment of the suspension line to a lateral end of the suspension line, the at least one transition zone having a thickness dimension that tapers from the second thickness dimension to the first thickness dimension,

wherein the elastomer does not coat all of the suture;

wherein the suture consists of a monolithic strand which continually runs the length of the suspension line such that the suture extends through the entire central segment of the suspension line defined by the elastomer; and

wherein the portion of the suture coated by the elastomer comprises a coiled section of the suture configured to provide limited compliance to the suspension line, such that the suspension line can be axially stretched to a stretched length greater than an unstretched length.

2. The suspension line of claim **1**, further comprising a plurality of transition zones, each transition zone extending from the central segment of the suspension line to respective lateral ends of the suspension line.

3. The suspension line of claim **1**, wherein the elastomer is overmolded onto the suture.

4. The suspension line of claim **1**, wherein the elastomer comprises silicone.

5. The suspension line of claim **1**, wherein the suture is braided.

6. The suspension line of claim **1**, further comprising a radiopaque marker operably attached to the suture.

7. The suspension line of claim **1**, wherein a radiopaque marker is disposed on the central segment of the suspension line.

8. The suspension line of claim **1**, wherein the suture extends axially along the entire length of the suspension line.

9. The suspension line of claim **1**, wherein the central segment of the suspension line comprises one or more knots for improving adhesion between the suture and the elastomer.

10. The suspension line of claim **1**, comprising a rounded cross-section.

11. The suspension line of claim **1**, comprising a rectangular cross-section.

12. The suspension line of claim 1, wherein the central segment is configured to move between a first axially unstretched configuration and a second axially stretched configuration.

13. A variable-thickness suspension line for suspending tissue, comprising:

a tether having a first thickness dimension, the tether having first and second lateral ends and a central segment; and

an elastomer coating and overmolded to the central segment of the tether and defining a central zone of the suspension line, the central zone having a second thickness dimension greater than the first thickness dimension,

wherein the elastomer does not coat all of the tether;

wherein the tether consists of a monolithic strand which continually runs the length of the suspension line such that the tether extends through the entire central zone of the suspension line defined by the elastomer; and

wherein the central segment of the tether coated by the elastomer comprises a coiled section of the tether configured to provide limited compliance to the suspension line, such that the suspension line can be axially stretched to a stretched length greater than an unstretched length.

14. A variable-thickness suspension line for suspending tissue, comprising:

a suture having a first thickness dimension; and

an elastomer coating a portion of the suture and defining a central segment of the suspension line having a second thickness dimension greater than the first thickness dimension, and at least one transition zone extending from the central segment of the suspension line to a lateral end of the suspension line, the at least one transition zone having a thickness dimension that tapers from the second thickness dimension to the first thickness dimension,

wherein the elastomer does not coat all of the suture;

wherein the suture consists of a monolithic strand which continually runs the length of the suspension line such that the suture extends through the entire central segment of the suspension line defined by the elastomer;

wherein the portion of the suture coated by the elastomer comprises a coiled section of the suture configured to provide limited compliance to the suspension line, such that the suspension line can be axially stretched to a stretched length greater than an unstretched length; and

wherein the elastomer comprises a smooth outer surface that is configured to facilitate the suspension line to pass through tissue.

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